Quality Improvement Assessment Guide for Medi-Cal Managed Care Plans

Medi-Cal Managed Care Division
California Department of
Health Care Services

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This QIA Guide for Plans was revised in November 2010 to reflect changes and enhancements to the validation process. Substantive changes are outlined by section below.

Documenting QIP Activities

Page 12—Information was added for documenting a multi-county QIP submission.

Page 13—QIP submission requirements were added for new plans or plan expansion.

How to Submit a QIP

Page 15—The Medi-Cal Managed Care QIPs mailbox for QIP submissions was added.

Appendix A—QIP Summary Form Completion Instructions

Page A-17—The critical element designation was removed from #1: *Data analysis was conducted according to the data analysis plan in the study design.*

Page A-17—Information was added to include an interpretation of the statistical testing under #4.

Page A-18—A critical element designation was added for #5: *The data analysis was presented in a way that provides accurate, clear, and easily understood information.*

Page A-18—Information was added to statistical testing under #7 to include a two-tailed approach and required *p* values.

Page A-18—Information was added to #9 to include further guidance for documenting the interpretation of the study's success.

Appendix B—QIP Summary Form Completion Instructions (multi-county)

New section

Appendix C—(previously Appendix B) QIP Validation Tool

Page C-12—The scoring methodology was updated to reflect the change in the critical element designation from Evaluation Element 1 to Evaluation Element 5.

References to validation "steps" were changed to "activities."

What is a Quality Improvement Project (QIP)?

A process of:

- Identifying a target area for improvement (clinical or nonclinical)
- Implementing interventions for improvement
- Analyzing results

Typically, QIPs are conducted in phases:

- Phase One—Study design and Baseline data collection
  - Plans target an area they want to improve upon and collect data to establish a starting point from which to measure improvement
- Phase Two—Implementation of improvement strategies
  - Plans identify and implement specific actions to correct problems they have identified
- Phase Three—Remeasurement and evaluation
  - Plans remeasure their performance after they have put their improvement efforts into place and evaluate if they were successful

Why do we do QIPs?

- *QIPs are a contract requirement for Medi-Cal managed care plans.* The California Department of Health Care Services (DHCS) requires each plan to conduct two QIPs that the DHCS must approve and DHCS's external quality review organization (EQRO) must validate.
- *QIPs are a federal requirement.* The Balanced Budget Act of 1997 (BBA), Public Law 105-33, requires that all states that operate a Medicaid managed care program ensure that their contracted plans conduct QIPs in accordance with the Code of Federal Regulations (CFR), at 42 CFR 438.240.[1]

[1] Balanced Budget Act of 1997. Federal Register/Vol. 67, No. 115, June 14, 2002, 2002/Rules and Regulations, p. 41109.

QIP side effects—the good news

Although the DHCS contract and the BBA require all plans to conduct QIPs, plans gain benefits by conducting QIPs. If conducted effectively, QIPs can:

- Improve performance measurement rates in non-targeted areas
- Keep plans focused on improving performance
- Improve member satisfaction

What are the responsibilities of plans, DHCS, and the EQRO?

- ***Plans*** design, document, and conduct the QIPs.
- The ***DHCS*** requires the QIPs and approves all new QIP proposals. The ***DHCS*** requires that one of the QIPs be either a plan-specific, internal QIP (IQIP) or a small-group collaborative QIP (SGC). The ***DHCS*** requires that the other QIP be the statewide collaborative QIP.
  - Specialty plans are required to conduct two IQIPs, as they do not participate in the statewide collaborative QIP.
  - For more details on DHCS QIP requirements, please refer to the plan contract or the most recent Medi-Cal Managed Care Division's *All Plan Letter* on annual quality improvement and performance measurement requirements. (All plan letters for the Medi-Cal Managed Care program are posted on the DHCS Web site at http://www.dhcs.ca.gov/services/Pages/Medi-CalManagedCare.aspx.)
- ***EQROs*** validate the QIPs to ensure that they are methodologically sound and meet all State and federal requirements. ***EQROs*** provide technical assistance to plans to help interpret QIP requirements.

Where can I find additional help?

Health Services Advisory Group, Inc. (HSAG) provides a list of resources and references in Section 7 of this guide that can aid plans in conducting QIPs.

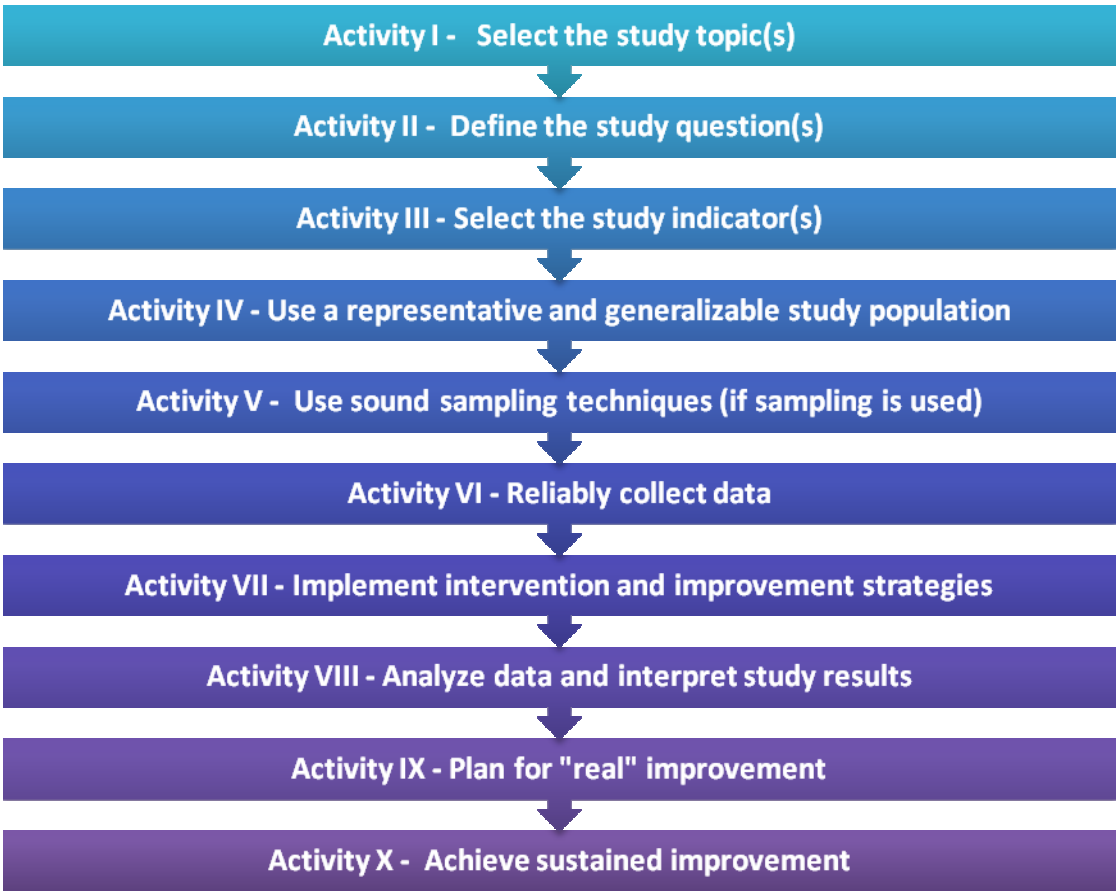
Section Organization

This section of the Quality Improvement Assessment Guide covers the following:

- The 10 activities outlined by the U.S. Department of Health and Human Services' Centers for Medicare & Medicaid Services (CMS) in conducting quality improvement projects
- How to document a QIP using HSAG's QIP Summary Form

QIP Activities

QIPs are expected to include 10 activities outlined by CMS in its protocols for conducting and validating performance improvement projects.[2]



[2] *Conducting Performance Improvement Projects: A Protocol for Use in Conducting Medicaid External Quality Review Activities, Final Protocol, Version 1.0, May 2002* and *Validating Performance Improvement Project: A Protocol for Use in Conducting Medicaid External Quality Review Activities, Final Protocol, Version 1.0, May 2002.*

Activity I: Selecting a Study Topic(s)

DHCS's Medi-Cal Managed Care Program typically allows plans to select IQIP and SGC topics, although the DHCS or CMS could specify the topic. Plans should select a study topic to target improvement in relevant areas of clinical care or nonclinical services. In selecting a topic, plans should consider areas where their performance needs improvement, including performance measures that are at or below the DHCS minimum performance level (MPL). Plans may also select a topic based on input from members.

Key Concepts

The study topic:

- Reflects high-volume or high-risk conditions
- Is selected following collection and analysis of data
- Addresses a broad spectrum of care and services
- Includes all eligible populations that meet the study criteria
- Does not exclude members with special health care needs
- Has the potential to affect member health, functional status, or satisfaction

Many QIPs include national benchmarks or cite current literature, but they neglect to connect the topic to their population. Lack of plan-specific documentation related to the study topic is a common reason a QIP does not fully meet the review criteria for this evaluation element.

Plans need to determine the extent to which they considered specific Medi-Cal enrollee demographic characteristics, prevalence of the chosen topic, or the need for a specific service.

Activity II: Defining the Study Question(s)

Defining the study question helps maintain the focus of the QIP and sets the framework for data collection, analysis, and interpretation. The study question should clearly state the question, in writing, that the study is designed to answer.

Key Concepts

The study question:

- States the problem to be studied in simple terms
- Is answerable

According to the CMS protocol for conducting QIPs, the study question should be in an X/Y format—i.e., *Does doing X result in Y?* A QIP aimed at decreasing the rate of avoidable ER visits might pose the study question as:

Do targeted interventions decrease the rate of avoidable ER visits during the measurement year?

Activity III: Selecting the Study Indicator(s)

A study indicator is a quantitative or qualitative characteristic or variable that reflects a discrete event (e.g., an older adult has not received an influenza vaccination in the last 12 months) or a status (e.g., a member's blood pressure is/is not below a specified level) that is to be measured. The selected indicators should track performance or improvement over time.

Key Concepts

The study indicator:

- Is well-defined, objective, and measurable
- Is based on current, evidence-based practice guidelines, pertinent peer-reviewed literature, or consensus reached by expert panels
- Allows for the study question to be answered
- Has data available for collection

Study indicators need to *answer* the study question; therefore, if HSAG determines that the study indicator does not answer the study question, the QIP would not fully meet the review criteria for this evaluation element.

Activity IV: Using a Representative and Generalizable Study Population

Plans should ensure that the study population includes all Medi-Cal plan members to which the study question applies. Once the plans identify the population, they should decide whether or not to review data for the entire population or a sample of that population. The plans also need to identify the length of a member's enrollment in the plan for inclusion in the study population.

Key Concepts

The study population:

- Is accurately and completely defined
- Includes requirements for the length of a member's enrollment in the plan
- Captures all members to whom the study question applies

QIPs that use Healthcare Effectiveness Data and Information Set (HEDIS®)[3] methodology need to include either a copy of the specifications or cite them completely. Plans that simply cite, for example, "HEDIS 2008" for the study population numerator and denominator do not meet the intent of this review element. Plans need to clearly define inclusions, exclusions, and diagnosis criteria.

Activity V: Using Sound Sampling Techniques

If a plan decides to use a sample instead of the entire population, the plan should use proper sampling techniques.

Key Concepts

Sampling methods use the entire population or:

- Consider and specify the true or estimated frequency of occurrence
- Identify the sample size
- Specify the confidence level to be used
- Specify the acceptable margin of error
- Ensure a representative sample of the eligible population
- Ensure accordance with generally accepted principles of research design and statistical analysis

[3] HEDIS® is a registered trademark of the National Committee for Quality Assurance (NCQA)

Plans that lack resources or expertise regarding sampling can find resources in Section 7 or they can consult with the EQRO for guidance.

Activity VI: Using Valid and Reliable Data Collection Procedures

Plans need to ensure that the data collected on QIP indicators are valid and reliable. Validity means the information collected is accurate. Reliability means the measures and data collected can be reproduced with the same results.

Key Concepts

Data collection ensures:

- The identification of data elements to be collected
- The identification of specified sources of data
- A defined and systematic process for collecting Baseline and remeasurement data
- A timeline for the collection of Baseline and remeasurement data

Manual data collection should include:

- Qualified staff and personnel to abstract manual data
- A manual data collection tool that ensures consistent and accurate collection of data according to indicator specifications
- A manual data collection tool that supports interrater reliability
- Clear and concise written instructions for completing the manual data collection tool
- An overview of the study in written instructions

Administrative data should include:

- Algorithms/flow charts that show steps in the production of indicators
- An estimated degree of administrative data completeness

The CMS protocol for conducting QIPs guides plans to include a data analysis plan that considers factors related to data collection, such as whether the plan will: use qualitative or quantitative data, include the entire population or a sample, compare the data collected to

previous or similar studies, and compare its QIP results to the performance of another plan(s). Plans that compare their QIP results or performance to previous studies or other entities need to include information on appropriate statistical testing and study design.

QIPs that use hybrid methodology need to include the data collection manual *instructions* and data collection *tool* to fully meet this evaluation element.

Activity VII: Implementing Intervention and Improvement Strategies

By picking the right interventions, plans are more likely to have QIPs that result in positive changes. Interventions can be designed to change behavior at an institutional, practitioner, or member level.

Key Concepts

Interventions are:

- Related to causes/barriers identified through data analysis and quality improvement (QI) processes
- System changes that are likely to induce permanent change
- Revised if the original interventions are not successful
- Standardized and monitored if interventions are successful

Once a plan defines a problem with supporting data/evidence, a causal/barrier analysis asks why the problem exists and identifies the causal relationships associated with the problem.

QIP reviewers look for documentation of the process used to conduct the causal/barrier analysis, such as a data analysis process or brainstorming sessions. QIPs that fail to describe the process used for causal/barrier analysis will not fully meet this evaluation element.

Plans should also document any delays with implementing interventions or deviations from the original timelines and provide information as to how they will address the delays.

Activity VIII: Analyzing Data and Interpreting Study Results

Plans determine how they are performing on the study indicators by analyzing the data collected and interpreting the results.

Key Concepts

Data analysis and interpretation:

- Are conducted according to the data analysis plan in the study design
- Allow for the generalization of results to the study population if a sample was selected
- Ensure the identification of factors that threaten internal or external validity
- Provide an interpretation of findings
- Are presented in a way that provides accurate, clear, and easily understood information
- Identify initial measurement and remeasurement of study indicators
- Identify statistical differences between initial measurement and remeasurement
- Identify factors that affect the ability to compare the Baseline measurement with remeasurement
- Include an interpretation of the extent to which the study was successful

The data analysis plan needs to include a description of how the plan will calculate its rates, how the plan will compare its rates with the QIP goals and benchmarks, and the statistical method the plan will use.

HSAG provides guidance and recommendations to plans on generally acceptable statistical methods and rationale.

Activity IX. Plan for "Real" Improvement

Plans need to determine if improved performance is just a one-time event or if it is a true and permanent change. To do this, plans calculate the extent to which changes in performance are statistically significant.

Testing for significance allows a plan to show that it is unlikely that improved performance is due to chance. Statistical significance helps to demonstrate that improvement is the result of the targeted interventions.

Key Concepts

"Real" improvement is based on:

- Remeasurement methodology that is the same as Baseline measurement methodology
- Documented improvement in processes or outcomes of care
- Improvement that appears to be the result of the intervention(s)
- Evidence that observed improvement is statistically significant

QIP reviewers will determine if the methodology remains the same for the Baseline and the remeasurement(s), or if the plan documented any change in methodology and the corresponding rationale.

Activity X. Achieve Sustained Improvement

Sustained improvement is a demonstration of real change rather than a one-time occurrence or an occurrence by chance.

Key Concept

Sustained improvement is based on:

- Repeated measurements over comparable time periods that demonstrate that improvement is statistically significant or that a decline in improvement is not statistically significant

Plans should provide a discussion of all the study indicators and whether they showed sustained improvement, a decrease that was not statistically significant, or lack of sustained improvement.

QIP Activity Additional Resources

Plans are encouraged to reference the CMS protocol for conducting QIPs for more detailed information on each of the 10 activities. The National Committee for Quality Assurance's (NCQA's) publication, *Health Care Quality Improvement Studies in Managed Care Settings, Design and Assessment: A Guide for State Medicaid Agencies,* provides guidance on each activity, as well. The *How to Get Help* section of this guide includes additional references.

The completion of these activities over time offers the plans a structure in which they can design and conduct quality improvement processes and demonstrate achievement. By following these activities, plans should be able to meet both the CMS protocol for conducting QIPs and the DHCS contractual requirements.

Documenting QIP Activities

How to Document a QIP Activity:

Plans will document their QIP proposals, annual submissions, and resubmissions using HSAG's QIP Summary Form. Appendix A includes a copy of the QIP Summary Form with detailed instructions. Appendix B contains a copy of the QIP Summary Form (multi-county), which plans will use to document a single QIP submission for multiple counties.

To get started, plans should use the completion instructions, which outline each evaluation element and provide detailed information on the required documentation. By referring to the completion instructions before completing each section of the QIP form, plans will know which elements to document. Use of the completion instructions simplifies QIP submissions by ensuring that plans address each evaluation element within the QIP documentation, reducing omissions of required documentation.

Plans should document the type of QIP initiated (i.e., statewide collaborative, IQIP, or SGC) under Activity I. Plans with contracts in multiple service areas may select the same QIP topic for all of their service areas; however, QIPs that cover multiple service areas will require measurement of improvement for each service area. Plans should thoroughly document any population differences between counties or regions. A sampling within each county represented may be necessary to evaluate for geographic differences.

HSAG conducts a "desk review" (i.e., no on-site visit or interviews) when validating QIPs; therefore, plans should make sure to provide thorough QIP documentation. For plans to get full credit upon validation, they should address each element within the sections of the QIP Summary Form. Plans should indicate when elements are not applicable to the project and

avoid leaving elements blank. In addition to the documentation provided on the QIP Summary Form, plans can include attachments that provide further documentation.

For annual submissions and resubmissions, plans should strikethrough deleted information on the QIP Summary Form and bold, highlight, and date any new information the plans add. The plans maintain the same submission document throughout the study. Plans should not use the track changes feature.

DHCS QIP Requirements:

The DHCS's Medi-Cal Managed Care Program requires both regular plans and specialty plans to always maintain two active QIP projects for each county they are operating in unless otherwise specified by the DHCS.

The DHCS designates a statewide Medi-Cal collaborative QIP for one of the two required projects for regular plans. The second QIP is either an IQIP or an SGC.

Plans contracting with the DHCS after the initiation of the current statewide collaborative are required to develop an IQIP or SGC in place of their participation in the statewide collaborative. New plans contracting with the DHCS or existing plans expanding into new counties are required to submit their QIP proposals to the DHCS once they have been in operation for 12 months. This allows plans time to collect data and conduct data analysis to support a QIP.

For specialty plans, the two QIPs are IQIPs or, with DHCS approval, specialty plans may replace one of the IQIPs with a plan or DHCS-facilitated SGC.

Section Organization

This section of the Quality Improvement Assessment Guide will cover the following:

- When to submit a QIP
- How to submit a QIP
- When to expect feedback

When to Submit a QIP

The DHCS requires plans to submit QIPs as follows:

New Proposals: Once plans complete the development of a new QIP using the CMS protocol for conducting a QIP and documenting the project on the HSAG QIP Summary Form, the plans submit the QIP to the DHCS for preliminary approval. Once the DHCS approves the proposed QIP, the DHCS submits the QIP to the EQRO for validation. A proposed QIP is fully approved once it passes the EQRO's validation review.

Plans must submit a new proposal to the DHCS within 90 days of closing out a QIP to maintain contract requirements of having two active QIPs. After validation, the EQRO notifies the plan and the DHCS that a QIP is complete, using the QIP Validation Tool, and the DHCS provides the plan with a new QIP proposal due date.

Annual Submission: The DHCS requires plans to submit a QIP status report at least annually using the HSAG QIP Summary Form. The reporting frequency depends on the individual QIP. The EQRO's validation review includes the due date for the next annual status report submission. The DHCS reminds plans of their next submission approximately two weeks before the due date.

Resubmissions: The EQRO may require plans to resubmit a QIP after validation review if the QIP receives a *Not Met* designation or if HSAG identifies concerns that the plan needs to address prior to the next annual submission.

How to Submit a QIP

Plans submit new QIP proposals directly to the DHCS for initial approval via the Medi-Cal Managed Care Program's QIPs mailbox at qipsmail@dhs.ca.gov. Plans should document QIP proposals using the HSAG QIP Summary Form completed through Activity IV or, if sampling techniques will be used, through Activity V. Plans should submit QIP proposals to the DHCS prior to baseline data collection to allow the EQRO an opportunity to provide feedback to the plan on the structure of the QIP and the study design after validation review.

Plans submit QIP annual submissions directly to HSAG using HSAG's file transfer protocol (FTP) Web site. The FTP site allows for the secure exchange of files between HSAG and external partners. The FTP site is compliant with the Health Insurance Portability and Accountability Act (HIPAA), although QIPs do not require the submission of member personal health information. In addition, the site allows for large files to be uploaded and downloaded. Plans must also submit a copy of their annual submissions to the DHCS via the QIPs mailbox.

The Web site can be accessed at www.hsag.com by clicking on the "Partners" tab. The Web site prompts users to enter their username and password. Users can upload QIP files under the "QIPs" folder. To request or change individual access to the FTP site, plans can contact Denise Driscoll at ddriscoll@hsag.com.

HSAG developed the FTP site to exchange information by uploading/downloading information. It is not intended to serve as a storage site; therefore, documents will be posted for a maximum of 60 days.

HSAG logs submitted QIP documents into an internal tracking form for validation review.

When to Expect Feedback

New Proposals: The DHCS reviews new proposals internally within four weeks of submission. Pending EQRO review, the DHCS sends plans a preliminary QIP approval notification. Within two weeks of DHCS's approval, HSAG reviews QIPs and provides written feedback to plans and the DHCS as to the appropriateness and feasibility of the project and whether the project is likely to produce valid and reliable results. HSAG then provides validation feedback to plans and the DHCS via e-mail and documents the next QIP submission due date.

Annual Submission: HSAG reviews QIP summary forms within two weeks of submission, evaluating the QIPs against CMS protocols and making a judgment about the validity and reliability of the findings. HSAG then sends validation feedback to plans and the DHCS on the completed QIP Validation Tool via e-mail and documents the next QIP submission due date.

Resubmissions: HSAG reviews plans' QIP resubmissions within 10 business days of submission to determine if the plans addressed areas of noncompliance or other concerns identified in the QIP Validation Tool. HSAG then sends an updated QIP Validation Tool with written feedback to plans and the DHCS via e-mail and documents the next QIP submission due date.

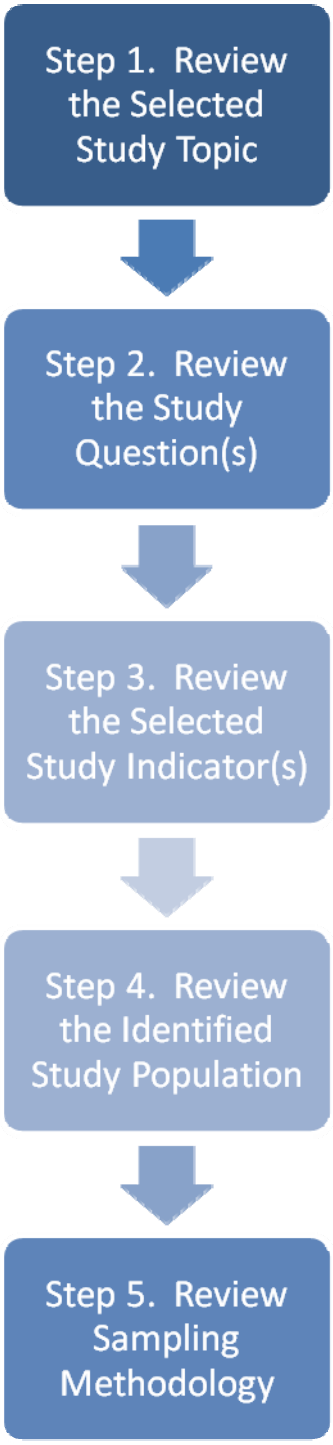
Section Organization

This section of the Quality Improvement Assessment Guide will cover HSAG's:

- 10 steps for QIP review
- QIP validation process
- QIP Validation Tool
- Scoring methodology
- Communication of validation results

10 Steps Used for QIP Review

For each QIP reviewed using the CMS protocol for validating QIPs as a guide, HSAG will, at a minimum, evaluate each activity using the following steps:



Step 1. Review the selected study topic(s) to assess if: data collection and analysis of plan member needs, care, and services support the necessity to conduct the QIP; the QIP targets improvement in relevant clinical and nonclinical care and services; the QIP is representative of the plan's Medicaid population; there are sufficient sources for data collection; and the plan can impact change in the area under study. Plans also may identify project topics by evaluating patterns of inappropriate utilization, or the State may select a project topic.

Step 2. Review the study question(s) to verify if it is clearly defined and answerable and if it is in the format to meet CMS requirements. The study question(s) will help maintain the focus of the QIP and set the framework for data collection, analysis, and interpretation.

Step 3. Review the selected study indicator(s) to determine if it: is measurable, is clearly defined, aligns with the study question(s), has adequate data sources, addresses limitations on collecting data, has clearly defined criteria for data collection, measures processes and outcomes of care, and has realistically set performance goals and benchmarks. Each project should have one or more quality indicators to track performance and improvement over time.

Step 4. Review the identified study population to determine: how the study population is defined, if all members relevant to the study question and indicators are included or a sample of these members are included, if there is any defined continuous enrollment criteria, and if the data collection plan ensures the capture of all members in the study population. Once the plan identifies the population, it must determine whether to review data for the entire population or select a sample of that population.

Step 5. Review sampling methods (if sampling is used) to determine: if the study sample is derived in accordance with generally accepted principles of research design and statistical analysis, is sufficient to make meaningful conclusions, and will provide valid and reliable results.

Step 6. Review data collection procedures to determine if: data collection techniques comply with industry standards; the plan performs data collection in a manner that preserves internal and external validity; the method for calculating indicators is appropriate; the algorithm for extracting automated information system (IS) data is sound/accurate; the manual data collection tool complies with indicator specifications and ensures accurate data collection; the plan provides clearly written instructions for completing the manual data collection tool, specific instructions on how to complete each section, and guidelines on how to handle situations not covered by the instructions; manual data collection staff resources are adequate and staff members are qualified; and the data validation process is effective in verifying the accuracy of the data collected.

Step 7. Assess improvement strategies to determine if the barrier analysis is adequate to identify barriers to improvement, the plan has developed appropriate improvement strategies, and the timeline for implementation of interventions is reasonable. The protocol defines an improvement strategy as "an intervention designed to change behavior at an institutional, practitioner, or beneficiary level." HSAG determines the effectiveness of the intervention activity or activities by measuring the plan's change in performance.

Step 8. Review data analysis and interpretation of study results to determine if data analysis techniques comply with industry standards, appropriate statistical tests are used, and accurate/reliable information is obtained. HSAG will also determine if the plan based its interpretation and analysis on continuous improvement philosophies, appropriately attributed causes/barriers to findings, and communicated study results to appropriate internal committees and external entities.

Step 9. Assess the likelihood that reported improvement is "real" improvement to verify if the plan has achieved significant improvement and if reported improvement in processes or outcomes of care is actual improvement. HSAG will assess the extent to which any changes in performance reported by the plan are statistically significant.

Step 10. Assess for sustained improvement to determine if the process can reasonably ensure continued improvement over time and if real change resulted from changes in health care delivery that can be documented by the plan.

QIP Validation Process

HSAG's approach to QIP validation activities provides a consistent, structured process and a mechanism for providing plans with specific feedback and recommendations for their QIPs. This structured method of assessing QIPs results in the improved reliability and validity of QIPs, supporting the ultimate goal of improving member health outcomes.

HSAG uses the CMS protocol for validating QIPs to develop its QIP validation process, including tools, internal review, and evaluation. HSAG's QIP Review Team routinely evaluates the validation process and makes changes using quality improvement tools and techniques. The team identifies opportunities to streamline the process and develop efficiencies without jeopardizing the integrity of the process, ensuring the validity and reliability of the results.

HSAG reviews and scores each QIP in its entirety with each submission. HSAG reviews the QIP only to the point that the study has progressed.

Key Concepts

QIP validation ensures that:

- QIPs are designed, implemented, and reported in a methodologically sound manner
- QIPs support the achievement of real improvement in the quality of care
- Documentation complies with CMS protocols for conducting QIPs
- Stakeholders can have confidence in the reported improvements

HSAG's QIP Review Team:

HSAG's QIP Review Team includes a minimum of two reviewers for each study to ensure reliability and appropriate determinations. Each review team consists of a clinician and a statistician.

Clinicians – registered nurses or licensed social workers – are certified professionals in healthcare quality (CPHQ) who have experience in physical and mental health care and have individually validated more than 400 QIPs conducted by Medicaid managed care plans across the country.

Statisticians bring a wealth of expertise to the validation process, including experience in study design, sampling, barrier analysis, and statistical testing.

HSAG uses a two-tiered approach to QIP validation. Each reviewer independently assesses the QIP submitted by the plan and then meets to discuss any scoring discrepancies to ensure scoring consistency. HSAG uses a resolution policy and procedure for resolving validation issues.

HSAG uses an internally-developed QIP Validation Tool to document validation findings and provide feedback to the plan on areas that need improvement. HSAG's goal is for the plans to score 100 percent on their QIP validation and to have a strong understanding of the CMS protocol for conducting a QIP and the quality improvement processes.

QIP Validation Tool

HSAG developed its QIP Validation Tool to assign objective findings to evaluation elements within each activity outlined in the CMS protocols. These evaluation elements are necessary for the successful completion of a valid QIP.

Of the 53 evaluation elements, HSAG designated 13 as critical elements. QIPs must receive a validation finding of *Met* on all critical evaluation elements for the QIP to be determined to be accurate and reliable. See Appendix B for a copy of HSAG's QIP Validation Tool.

QIP Scoring Methodology

HSAG's scoring methodology is consistent with CMS guidelines as outlined in the CMS publication, *Validating Performance Improvement Projects: A Protocol for Use in Conducting Medicaid External Quality Review Activities*, Final Protocol, Version 1.0, May 1, 2002.

Using the scoring methodology, HSAG evaluates plan QIPs to determine if they are valid and reliable and to what extent they are compliant with the CMS protocol for conducting a QIP.

Scoring critical and noncritical elements:

During validation, HSAG scores each evaluation element as *Met, Partially Met, Not Met, Not Applicable,* or *Not Assessed.*

Critical elements, located in the column to the left of the evaluation element, are essential to producing a valid and reliable QIP. Therefore:

- Each critical element must have a score of *Met* for the QIP to receive an overall *Met* validation status

- Critical elements that are *Partially Met* will not invalidate the QIP, but they will affect the overall percentage score
- Any critical element scored as *Not Met* will mean the QIP is not credible

For example, in Review Activity II of the QIP Validation Tool, if the study question could not be answered, then the critical element is scored as *Not Met* and the QIP is not credible.

Noncritical elements, individually, are not essential to producing a valid and reliable QIP. Noncritical elements receiving a finding of *Partially Met* or *Not Met* will not invalidate the QIP, but they will affect the overall percentage score, which reflects the degree of the QIP's overall compliance with the CMS protocol for conducting a QIP.

After HSAG scores each QIP evaluation element, a table, such as the Table 5-1 example below, shows total scores for all critical and noncritical elements.

Table 5-1—Quality Improvement Project Scores *for* QIP Topic Title *for* Name of Plan										
Review Activity	**Total Possible Evaluation Elements** (Including Critical Elements)	**Total *Met***	**Total *Partially Met***	**Total *Not Met***	**Total *NA***	**Total Possible Critical Elements**	**Total Critical Elements *Met***	**Total Critical Elements *Partially Met***	**Total Critical Elements *Not Met***	**Total Critical Elements *NA***
I. Select the Study Topic(s)	6	6	0	0	0	1	1	0	0	0
II. Define the Study Question(s)	2	2	0	0	0	2	2	0	0	0
III. Select the Study Indicator(s)	7	6	0	0	1	3	3	0	0	0
IV. Use a Representative and Generalizable Study Population	3	3	0	0	0	2	2	0	0	0
V. Use Sound Sampling Methods	6	0	0	0	6	1	0	0	0	1
VI. Reliably Collect Data	11	4	0	2	5	1	0	0	0	1
VII. Implement Intervention and Improvement Strategies	4	3	0	0	1	1	1	0	0	0
VIII. Analyze Data and Interpret Study Results	9	8	0	0	1	2	1	0	0	1
IX. Plan for Real Improvement	6	6	0	0	0	No Critical Elements				
X. Achieve Sustained Improvement	1	Not Assessed				No Critical Elements				
Totals for All Activities	**53**	**33**	**3**	**2**	**14**	**13**	**10**	**0**	**0**	**3**

Calculating the Percentage Scores:

HSAG calculates two percentage scores for QIPs using the critical and noncritical evaluation element scores (see example in Table 5-2):

- The Percentage Score of Evaluation Elements *Met*
- The Percentage Score of Critical Elements *Met*

The Percentage Score of Evaluation Elements *Met* is calculated by dividing the total number of elements, both critical and noncritical, that were *Met* by the sum of the total number of elements that were *Met*, *Partially Met*, and *Not Met*. This calculation excludes any elements designated as *Not Applicable* or *Not Assessed*.

The Percentage Score of Critical Elements *Met* is calculated by dividing the total number of critical elements *Met* by the sum of the critical elements *Met*, *Partially Met*, and *Not Met*. This calculation excludes any elements designated as *Not Applicable* or *Not Assessed*.

Table 5-2—Quality Improvement Project Overall Score *for* QIP Topic Title *for* Name of Plan

Percentage Score of Evaluation Elements *Met*	**87%**
Percentage Score of Critical Elements *Met*	**100%**
Validation Status*	***Met***

* *Met* equals confidence/high confidence that the QIP was valid.
Partially Met equals low confidence that the QIP was valid.
Not Met equals reported QIP results that were not credible.

Calculating the Validation Status:

The validation status is based on the percentage scores and whether or not critical elements were *Met*, *Partially Met*, or *Not Met*.

Not Assessed is used when the QIP has not progressed to the remaining activities in the CMS protocol for conducting a QIP. This includes QIP proposals for which plans have not yet implemented interventions, QIP Baseline submissions that do not have remeasurement data, or QIP resubmissions that do not include multiple remeasurement periods to assess for sustained improvement.

Points of Clarification are included for evaluation elements with a *Met* score that need enhanced documentation. *Points of Clarification* do not affect scores. However, if a plan does not address a *Point of Clarification* in future submissions, HSAG will negatively score the evaluation element in the next validation cycle.

Overall scores determine the overall QIP validation status as follows:

Met	• All critical elements were *Met* - ***and*** - • 80 to 100 percent of all elements were *Met* across all activities.
Partially Met	• All critical elements were *Met* **and** 60 to 79 percent of all elements were *Met* across all Activities -**or**- • One or more critical element(s) were *Partially Met* and the percentage score for all elements across all activities was 60 percent or more.
Not Met	• All critical elements were *Met* **and** less than 60 percent of all elements were *Met* across all activities -**or**- • One or more critical element(s) were *Not Met*.
Not Applicable (NA)	• *Not Applicable* elements (including critical elements) were removed from all scoring.
Not Assessed	• *Not Assessed* elements (including critical elements) were removed from all scoring.
Point of Clarification	• *Points of Clarification* occur when documentation for an evaluation element has the basic components described in the narrative of the QIP to meet the evaluation element; however, enhanced documentation would demonstrate a stronger understanding of the CMS protocol.

HSAG designed the scoring methodology to ensure that critical elements are must-pass evaluation elements. If one critical evaluation element is *Not Met*, the overall validation status is *Not Met*. In addition, the methodology addresses the potential situation in which HSAG scores all critical elements as *Met*, but finds suboptimal performance in the noncritical elements. HSAG bases the final outcome of the QIP's validation on the percentage score of critical elements met.

Evaluation of the Overall Validity and Reliability of QIP Results

For each QIP completed, HSAG assesses the validity and reliability of the findings based on the CMS protocol for validating QIPs and informs plans and the DHCS of the confidence level of the reported findings. HSAG assesses threats to the validity and reliability of the QIP findings and determines when an accumulation of threats reaches the point at which the findings are no longer credible. Using the QIP Validation Tool and standardized scoring methodology, HSAG reports overall validity and reliability to the DHCS.

HSAG reports validity and reliability as follows:

- *Met* = Confidence/high confidence in the reported QIP results
- *Partially Met* = Low confidence in the reported QIP results
- *Not Met* = Reported QIP results that were not credible

Communication of Validation Results

HSAG communicates QIP validation results via the QIP Validation Tool, which includes validation scoring and an overall validation status. The validation tool includes HSAG's feedback through *Points of Clarification* and comments related to evaluation elements receiving a *Partially Met* or *Not Met* score. The completed validation tool displays areas in which the plans need to provide additional documentation and the specific documentation needed to achieve a *Met* finding.

The *Next Steps* section provides direction to plans related to the findings.

Next Steps for Valid and Reliable QIPs:

- Plans will proceed with the QIP study and submit baseline results.
- Plans will continue the QIP for the next annual submission
- HSAG will instruct plans to address all *Partially Met* and *Not Met* scores and *Points of Clarification* prior to the next submission
- If HSAG validates the QIP through all 10 activities, HSAG considers the QIP final and advises the plan to submit a new QIP proposal to DHCS for approval within 90 days

Next Steps for Invalid or Unreliable QIPs:

- HSAG directs plans to resubmit a revised QIP addressing all *Partially Met* and *Not Met* scores and *Points of Clarification*

Communication with Plans and DHCS

HSAG provides a completed QIP Validation Tool to plans and the DHCS. Plans can contact the EQRO directly to discuss validation findings or request technical assistance.

As required by its DHCS contract, HSAG prepares a Quarterly QIPs Status Report that includes a list of all QIPs validated during the quarter. The report documents:

- Aggregate validation findings for the quarter
- Strengths and opportunities for improvement identified through the validation process
- Recommendations provided to the DHCS and the plans
- A list of all active QIPs conducted by the plans
- Key findings and best practices

Technical Assistance

HSAG is available to provide technical assistance to plans to ensure that their QIPs are sound and valid and result in real improvements in the care and/or services provided to Medi-Cal members. HSAG also provides technical assistance to help plans comply with CMS protocol requirements.

HSAG's approach to providing technical assistance focuses on several key areas:

- Providing information to the DHCS and plans regarding the validation process, criteria, and related federal requirements/protocols
- Providing information to the DHCS and plans regarding supporting materials that plans should submit to meet validation requirements
- Assisting in the development and monitoring of a statewide collaborative QIP to ensure that all QIP components meet CMS requirements
- Providing information on industry standard practices for conducting QIPs
- Providing meaningful and timely feedback to plans regarding each QIP
- Conducting follow-up conference calls with plans to discuss evaluation results if requested and/or approved by the DHCS
- Assisting plans in determining the possible reasons that QIPs have not achieved improvement and providing recommendations for improvement to the DHCS and the plans
- Identifying best practices, common issues, and performance trends and conveying this information to the DHCS and the plans
- Assisting in educating the DHCS and the plans regarding pertinent quality improvement project study areas

HSAG provides technical assistance through e-mails, conference calls, and/or Webinars. With DHCS approval, HSAG may provide Webinars to respond to global questions with answers that would benefit all the plans. Plans may request technical assistance through the DHCS and HSAG points of contact.

HSAG provides the following list of resources and references to help plans in conducting QIPs. These sites offer protocols, literature, guidelines, and tools used for quality improvement projects.

- **Agency for Healthcare Research and Quality—**The nation's leading federal agency for research on health care quality, costs, outcomes, and patient safety. www.ahrq.gov
- **Agency for Healthcare Research and Quality**—Health plans send this agency the innovations and/or tools they used to improve services provided to their members. Information includes innovations that did not work and why, and the level of evidence (strong, moderate, low, insufficient). www.innovations.ahrq.gov
- **Center for Healthcare Strategies**—A nonprofit health policy resource center dedicated to improving the quality and cost effectiveness of health care services for low-income populations and people with chronic illnesses and disabilities. www.chcs.org
- **Centers for Medicare & Medicaid Services (CMS)**—The U.S. Department of Health and Human Services agency responsible for administering the Medicare, Medicaid, CHIP (Children's Health Insurance Program), and several other health-related programs. www.cms.hhs.gov
  - *Conducting Performance Improvement Projects: A Protocol for Use in Conducting Medicaid External Quality Review Activities, Final Protocol, Version 1.0, May 2002, and Validating Performance Improvement Projects: A Protocol for Use in Conducting Medicaid External Quality Review Activities, Final Protocol, Version 1.0, May 2002.*

    These external quality review (EQR) managed care organization (MCO) protocols are available at:
    http://www.cms.hhs.gov/MedicaidSCHIPQualPrac/07_Tools_Tips_and_Protocols.asp
- **The National Committee for Quality Assurance** is a private, nonprofit organization dedicated to improving health care quality. NCQA has been a central figure in driving improvement throughout the health care system, helping to elevate the issue of health care quality to the top of the national agenda. www.ncqa.org
  - *Health Care Quality Improvement Studies in Managed Care Settings, A Guide for State Medicaid Agencies.*
- **Institute for Healthcare Improvement (IHI)**—An independent, nonprofit organization helping to lead the improvement of health care throughout the world. IHI works to accelerate improvement by building the will for change, cultivating promising concepts for improving patient care and helping health care systems put those ideas into action. www.ihi.org

- **National Guideline Clearinghouse (NGC)**—A public resource for evidence-based clinical practice guidelines, NGC is an initiative of the Agency for Healthcare Research and Quality (AHRQ), U.S. Department of Health and Human Services. AHRQ originally created NGC in partnership with the American Medical Association and the American Association of Health Plans (now America's Health Insurance Plans [AHIP]). www.guidelines.gov
- Sampling Calculator—An online calculator that can be used to determine sample sizes. http://www.surveysystem.com/sscalc.htm
- Statistical Testing Calculator—An online statistical calculator that can be used to perform statistical testing. www.graphpad.com/quickcalcs/index.cfm

CMS

Centers for Medicare & Medicaid Services (CMS) is the federal agency responsible for administration of the Medicare and Medicaid programs. This agency was formerly known as the Health Care Financing Administration (HCFA).

CMS Protocols

A written instructional document for conducting specific EQR-related activities, including conducting and validating MCO QIPs.

Critical Element

Elements within the EQRO QIP Validation Tool that have been identified as essential for producing a valid and reliable QIP. All critical elements must be *Met* for a QIP to receive an overall validation status of *Met*.

EQRO

An external quality review organization (EQRO) is a peer review organization (PRO)-like entity or accrediting body that has expertise in reviewing the quality of health care provided to Medicaid beneficiaries in a state's Medicaid managed care plans. CMS requires state Medicaid managed care programs to contract with an EQRO to receive enhanced federal financial participation.

Noncritical Element

Elements within the EQRO QIP Validation Tool that have been identified as nonessential for producing a valid and reliable QIP. Noncritical elements are included in the total sum to produce an overall QIP validation percentage score.

Outcome Measure

Variables that measure the end results of health care—e.g., elimination of disease, improvement of functioning or perceived well-being, birth weight, or death.

Performance Improvement Project (PIPs)

The federal term for QIPs. A structured process of identifying and measuring a targeted area (clinical or nonclinical), analyzing the results, implementing interventions for improvement, and remeasuring to determine if improvement in performance was achieved.

Points of Clarification

Comments provided by the EQRO on the QIP Validation Tool to indicate that documentation for an evaluation element has the basic components; however, enhanced documentation would demonstrate a stronger understanding of the CMS protocol.

Quality Improvement Projects (QIPs)

A structured process of identifying and measuring a targeted area (clinical or nonclinical), analyzing the results, implementing interventions for improvement, and remeasuring to determine if improvement in performance was achieved.

Reliability

The degree to which a measure is reproducible—i.e., whether the measure has the same result when applied repeatedly.

Sampling

The process of selecting a representative part of an overall population to study characteristics or test a hypothesis.

Statistical Significance

Quantifies the degree to which sampling variability may account for the results observed in a particular study.

Technical Assistance

The process of providing information on specific technical content related to EQR activities to address an identified need.

Validation

An objective review of a QIP by an EQRO to determine compliance with the CMS requirements for conducting a valid QIP.

Validity

The extent to which the data collected for a QIP accurately measure what they were intended to measure and whether the conclusions made from the QIP were appropriate and justifiable.

Appendix A. California Medi-Cal Managed Care Program
Quality Improvement Projects
QIP Summary Form Completion Instructions

Each section provides guidance based on CMS' protocols for how to document the QIP. HSAG provides specific comments for individual plans during the QIP evaluation and validation process.

DEMOGRAPHIC INFORMATION	
Plan Name: **<Full Name>**	
Study Leader Name: _____	Title: _____
Telephone Number: _____	E-Mail Address: _____
Name of Project/Study: ***<QIP Topic>***	
County/Counties Reported: _____	
Type of Study: ☐ Clinical ☐ Nonclinical ☐ HEDIS ☐ IQIP ☐ SGC ☐ Statewide Collaborative	**Section to be completed by HSAG** _____ Year 1 Validation _____ Initial Submission _____ Resubmission _____ Year 2 Validation _____ Initial Submission _____ Resubmission _____ Year 3 Validation _____ Initial Submission _____ Resubmission
Date of Study: _____ to _____	_____ Baseline Assessment _____ Remeasurement 2 _____ Remeasurement 1 _____ Remeasurement 3
Type of Delivery System: MCP	
Number of Medi-Cal Members in Plan _____ Number of Medi-Cal Members in Study _____	Year 1 validated through Activity _____ Year 2 validated through Activity _____ Year 3 validated through Activity _____
Type of Submission: ☐ Proposal ☐ Annual Submission ☐ Resubmission Submission Date: _____	

A. Activity I: Select the study topic. QIP topics should target improvement in relevant areas of services and reflect the population in terms of demographic characteristics, prevalence of disease, and the potential consequences (risks) of disease. Topics may be derived from utilization data (ICD-9 or CPT coding data related to diagnoses and procedures; NDC codes for medications; HCPCS codes for medications, medical supplies, and medical equipment; adverse events; admissions; readmissions; etc.); grievances and appeals data; survey data; provider access or appointment availability data; member characteristics data such as race/ethnicity/language; other fee-for-service data; or local or national data related to Medicaid risk populations. The goal of the project should be to improve processes and outcomes of health care or services in order to have a potentially significant impact on member health, functional status, or satisfaction. The topic may be specified by the state Medicaid agency or CMS, or it may be based on input from members. Over time, topics must cover a broad spectrum of key aspects of member care and services, including clinical and nonclinical areas, and should include all enrolled populations (i.e., certain subsets of members should not be consistently excluded from studies).

Study topic:

Clearly state the study topic. Specify if the topic was assigned by the State. Explain how the study topic was selected, addressing the following required HSAG evaluation elements:

1. Reflects high-volume or high-risk conditions.

- The narrative should describe how the study topic reflects a high-volume or high-risk condition or service for the plan.
- If the study topic was selected by the California DHCS, this must be specified in the QIP Summary Form.

2. Is selected following collection and analysis of data.

- Provide plan-specific data collection and analysis to support the selection of the study topic.
- If no plan-specific data were available, provide rationale for why it was not included.

3. Addresses a broad spectrum of care and services.

- For clinical focus areas, the study topic should include prevention and care of acute and chronic conditions and high-volume/high-risk services.
- For non-clinical focus areas, continuity of care should be addressed in a manner in which care was provided from multiple providers across multiple episodes of care.
- Additionally, topics such as member satisfaction or the over utilization of emergency room services might also be appropriate.

A. Activity I: Select the study topic. QIP topics should target improvement in relevant areas of services and reflect the population in terms of demographic characteristics, prevalence of disease, and the potential consequences (risks) of disease. Topics may be derived from utilization data (ICD-9 or CPT coding data related to diagnoses and procedures; NDC codes for medications; HCPCS codes for medications, medical supplies, and medical equipment; adverse events; admissions; readmissions; etc.); grievances and appeals data; survey data; provider access or appointment availability data; member characteristics data such as race/ethnicity/language; other fee-for-service data; or local or national data related to Medicaid risk populations. The goal of the project should be to improve processes and outcomes of health care or services in order to have a potentially significant impact on member health, functional status, or satisfaction. The topic may be specified by the state Medicaid agency or CMS, or it may be based on input from members. Over time, topics must cover a broad spectrum of key aspects of member care and services, including clinical and nonclinical areas, and should include all enrolled populations (i.e., certain subsets of members should not be consistently excluded from studies).

4. Includes all eligible populations that meet the study criteria.

- Explain if all eligible populations that met the study criteria were included in the study.
- The eligible population for the QIP should be described in Activity I.
- If the eligible population was selected by the California DHCS, there must be reference to that in the QIP Summary Form.

5. Does not exclude members with special health care needs.

- Include a statement about the inclusion or exclusion of members with special health care needs.
- If members with special health care needs were excluded from the study, explain why.

6. Has the potential to affect member health, functional status, or satisfaction. (Critical Element)

- The narrative should explain how the study topic has the potential to affect member health, functional status, or satisfaction.
- The link between the study topic and outcomes of care should be explained in Activity I.

B. Activity II: Define the study question(s). Stating the question(s) helps maintain the focus of the QIP and sets the framework for data collection, analysis, and interpretation.

Study question:

Enter written QIP study question(s) here. Ensure the study question(s) addresses the following HSAG evaluation elements:

1. States the problem to be studied in simple terms. (Critical Element)

- Per CMS' protocol, the study question(s) should be stated in the format, "Does doing X result in Y?"
- Define terms used in the study question(s) that might not be clear.

2. Is answerable. (Critical Element)

- The study question(s) must be answerable through the proposed data collection methodology and study indicator(s) provided.

C. Activity III: Select the study indicator(s). A study indicator is a quantitative or qualitative characteristic or variable that reflects a discrete event (e.g., an older adult has not received an influenza vaccination in the last 12 months) or a status (e.g., a member's blood pressure is/is not below a specified level) that is to be measured. The selected indicators should track performance or improvement over time. The indicators should be objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research.

Study indicators:

List any details or background information about the indicator(s) and how they were selected.

Enter the study indicator(s) in the table for Activity III, ensuring that, at a minimum:

1. The indicator(s) are well-defined, objective, and measurable. **(Critical Element)**

- Provide study indicator(s) that are objective and measurable. Complete descriptions of the numerators and denominators should be provided.
- Define terms used in the indicator(s). Include any codes used to define numerator events.
- Provide the description/rationale for each study indicator(s).
- Include all starting and ending dates for all measurement periods.

2. Are based on current, evidence-based practice guidelines, pertinent peer-reviewed literature, or consensus expert panels.

- Study indicator(s) should be based on current clinical practice guidelines or health services research, and these sources should be specified in the QIP documentation.
- If the study indicator(s) is not based on any of the above, the documentation should include this.
- If the study indicator(s) was provided by the State, the documentation in Activity III should include this.

3. The indicator(s) allow for the study question to be answered. (Critical Element)

- The study indicator(s) should provide data to answer the reported study question(s).
- The study indicator(s) and study question(s) should align.

C. Activity III: Select the study indicator(s). A study indicator is a quantitative or qualitative characteristic or variable that reflects a discrete event (e.g., an older adult has not received an influenza vaccination in the last 12 months) or a status (e.g., a member's blood pressure is/is not below a specified level) that is to be measured. The selected indicators should track performance or improvement over time. The indicators should be objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research.

4. The indicator(s) measure changes (outcomes) in health or functional status, member satisfaction, or valid process alternatives.

- The study indicator(s) must objectively measure member outcomes such as health, functional status, and/or member satisfaction or valid process alternatives.

5. The indicator(s) have available data that can be collected on each indicator. (Critical Element)

- Data should be available through administrative sources, medical records, surveys, or other readily available sources.

6. The study indicators are nationally recognized measures, such as HEDIS technical specifications, when appropriate.

- When appropriate, nationally recognized measures, such as HEDIS, should be used.
- If the study indicator(s) are nationally recognized measures, this should be explained in the QIP documentation. The year of the specifications should also be included, and updated annually, if appropriate.

7. Include the basis on which indicator(s) was adopted, if internally developed.

- If the study indicator(s) were internally developed, the rationale and explanation why each study indicator(s) was chosen for the QIP should be provided in the QIP Summary Form.

C. Activity III: Select the study indicator(s). A study indicator is a quantitative or qualitative characteristic or variable that reflects a discrete event (e.g., an older adult has not received an influenza vaccination in the last 12 months) or a status (e.g., a member's blood pressure is/is not below a specified level) that is to be measured. The selected indicators should track performance or improvement over time. The indicators should be objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research.	
Study Indicator 1	**Describe the rationale for selection of the study indicator:**
Numerator: (no numeric value)	
Denominator: (no numeric value)	
Baseline Measurement Period	
Baseline Goal	
Remeasurement 1 Period	
Remeasurement 2 Period	
Benchmark	
Source of Benchmark	
Study Indicator 2	**Describe the rationale for selection of the study indicator:**
Numerator: (no numeric value)	
Denominator: (no numeric value)	
Baseline Measurement Period	
Baseline Goal	
Remeasurement 1 Period	
Remeasurement 2 Period	
Benchmark	
Source of Benchmark	

C. Activity III: Select the study indicator(s). A study indicator is a quantitative or qualitative characteristic or variable that reflects a discrete event (e.g., an older adult has not received an influenza vaccination in the last 12 months) or a status (e.g., a member's blood pressure is/is not below a specified level) that is to be measured. The selected indicators should track performance or improvement over time. The indicators should be objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research.

Study Indicator 3	**Describe the rationale for selection of the study indicator:**
Numerator: (no numeric value)	
Denominator: (no numeric value)	
Baseline Measurement Period	
Baseline Goal	
Remeasurement 1 Period	
Remeasurement 2 Period	
Benchmark	
Source of Benchmark	

Use this area to provide additional information. Discuss the guidelines used and the basis for each study indicator.

D. Activity IV: Use a representative and generalizable study population. The selected topic should represent the entire eligible population of Medicaid members with systemwide measurement and improvement efforts to which the study indicators apply. Once the population is identified, a decision must be made whether or not to review data for the entire population or a sample of that population. The length of members' enrollment needs to be defined to meet the study population criteria.

Study population:

Describe the population and methods for identifying the study population. Identify the study population, addressing the following HSAG evaluation elements:

1. The study population is accurately and completely defined. (Critical Element)

- Clearly define inclusion, exclusion, and diagnosis criteria.
- Include a list of diagnosis codes or system codes used to identify members.
- Include any anchor dates used to identify age criteria.

2. The study population includes requirements for the length of a member's enrollment in the plan.

- Define continuous enrollment, new enrollment, and allowable gaps in enrollment.
- Any dates used to identify continuous enrollment criteria should be included.

3. The study population captures all members to whom the study question applies. (Critical Element)

- The eligible population should include all members to whom the study question applies.

E. Activity V: Use sound sampling techniques. If sampling is used to select members of the study, proper sampling techniques are necessary to provide valid and reliable information on the quality of care provided. The true prevalence or incidence rate for the event in the population may not be known the first time a topic is studied.

Sampling methods:
Enter sampling techniques used to select members for the study. Make sure that the responses address all HSAG evaluation elements below. If the entire eligible population was used, document this in Activity V of the QIP Summary Form.

Use the entire population, or

1. Consider and specify the true or estimated frequency of occurrence.

- The true or estimated frequency of occurrence should be considered in the sampling equation.

2. Identify the sample size.

3. Specify the confidence level to be used.

4. Specify the acceptable margin of error.

5. Ensure a representative sample of the eligible population. (Critical Element)

- Representative sampling techniques should be used to ensure generalizable information. For example, include the process used to select the study sample.
- If NCQA certified software is used to select the sample, include the certified software seal.

6. Are in accordance with generally accepted principles of research design and statistical analysis.

- Valid sampling techniques should be used for all study indicators, which can be replicated using the reported results.

Measure	Sample Error and Confidence Level	Sample Size	Population	Method for Determining Size (*describe*)	Sampling Method (*describe*)

F. Activity VIa: Reliably collect data. Data collection must ensure that the data collected on QIP indicators are valid and reliable. Validity is an indication of the accuracy of the information obtained. Reliability is an indication of the repeatability or reproducibility of a measurement.

Data Collection:

Enter data collection techniques. Make sure that the responses address all HSAG evaluation elements below:

1. Identification of data elements to be collected.

- Documentation should include clear definitions of the data elements to be collected.
- If using HEDIS, submit the HEDIS Compliance Final Audit Report.

2. Identification of specified sources of data.

- The sources of data should be clearly specified.

3. A defined and systematic process for collecting Baseline and remeasurement data.

- A systematic method for data collection should be specified.
- If an NCQA vendor was used to collect data, include the vendor's name.

4. A timeline for the collection of Baseline and remeasurement data.

- The timeline should include both starting and ending dates for Baseline and all measurement periods.

IF MANUAL DATA COLLECTION WAS USED:

5. Qualified staff and personnel to abstract manual data.

- The relevant education, experience, and training of all manual data collection staff should be described in the QIP Summary Form.

6. A manual data collection tool that ensures consistent and accurate collection of data according to indicator specifications. (Critical Element)

- Include the manual data collection tool with the QIP submission.
- For mailed surveys, include the cover letter and survey.
- For telephone surveys, include the script as well as the monitoring and training process for the telephone survey staff.

F. Activity VIa: Reliably collect data. Data collection must ensure that the data collected on QIP indicators are valid and reliable. Validity is an indication of the accuracy of the information obtained. Reliability is an indication of the repeatability or reproducibility of a measurement.

7. A manual data collection tool that supports interrater reliability (IRR).

- Include a discussion of the IRR process.

8. Clear and concise written instructions for completing the manual data collection tool.

- Written instructions for the manual data collection tool should be clearly and succinctly written and included with the QIP submission.

9. An overview of the study in written instructions.

- A brief statement about the purpose of the study should be included in the written instructions for the manual data collection tool.

IF ADMINISTRATIVE DATA WERE COLLECTED:

10. Administrative data collection algorithms/flow charts that show activities in the production of indicators.

- Documentation should include a systematic process of an ordered sequence of steps. Each step depends on the outcome of the previous step. This can be defined in a narrative, or with algorithms/flow charts.

11. An estimated degree of administrative data completeness.

- The estimated degree of administrative data completeness and a description of the process used for that determination should be included.

F. Activity VIa: Reliably collect data. Data collection must ensure that the data collected on QIP indicators are valid and reliable. Validity is an indication of the accuracy of the information obtained. Reliability is an indication of the repeatability or reproducibility of a measurement.

Data Sources

[ ] Hybrid (medical/treatment records and administrative)

[ ] Medical/Treatment Record Abstraction

Record Type

[ ] Outpatient
[ ] Inpatient
[ ] Other _____

Other Requirements

[ ] Data collection tool attached
[ ] Data collection instructions attached
[ ] Summary of data collection training attached
[ ] IRR process and results attached

[ ] Other data

Description of data collection staff (include training, experience, and qualifications):

[ ] Administrative Data

Data Source

[ ] Programmed pull from claims/encounters
[ ] Complaint/appeal
[ ] Pharmacy data
[ ] Telephone service data /call center data
[ ] Appointment/access data
[ ] Delegated entity/vendor data _____
[ ] Other _____

Other Requirements

[ ] Data completeness assessment attached
[ ] Coding verification process attached

[ ] Survey Data

Fielding Method

[ ] Personal interview
[ ] Mail
[ ] Phone with CATI script
[ ] Phone with IVR
[ ] Internet
[ ] Other _____

Other Requirements

[ ] Number of waves _____
[ ] Response rate _____
[ ] Incentives used _____

F. Activity VIb: Determine the data collection cycle.	**Determine the data analysis cycle.**
[ ] Once a year [ ] Twice a year [ ] Once a season [ ] Once a quarter [ ] Once a month [ ] Once a week [ ] Once a day [ ] Continuous [ ] Other (list and describe): _____ _____ _____	[ ] Once a year [ ] Once a season [ ] Once a quarter [ ] Once a month [ ] Continuous [ ] Other (list and describe): _____ _____ _____ _____ _____

F. Activity VIc. Data analysis plan and other pertinent methodological features.

Estimated degree of administrative data completeness: _____ percent.

Describe the process used to determine data completeness and accuracy.

Supporting documentation:

_____
_____
_____

G. Activity VIIa: Implement intervention and improvement strategies. (Interventions for improvement as a result of analysis). List chronologically the interventions that have had the most impact on improving the measure. Describe only the interventions and provide quantitative details whenever possible (e.g., "Hired four customer service representatives" as opposed to "Hired customer service representatives"). Do not include intervention planning activities.

Date Implemented (MM / YY)	Check if Ongoing	Interventions	Barriers That Interventions Address

G. Activity VIIb: Implement intervention and improvement strategies. Real, sustained improvements in care result from a continuous cycle of measuring and analyzing performance, as well as, developing and implementing systemwide improvements in care. Describe interventions designed to change behavior at an institutional, practitioner, or member level.

Interventions:

Describe interventions/improvement strategies for each measurement period. The interventions/improvement strategies should address the following HSAG required evaluation elements:

1. **Whether they are related to causes/barriers identified through data analysis and quality improvement (QI) processes. (Critical Element)**
   - Describe the causal/barrier analysis process used and explain how the intervention(s) were related to causes/barriers identified through data analysis and quality improvement processes.
2. **Whether they are system changes that are likely to induce permanent change.**
   - Select and include in the documentation, system interventions that will likely have a permanent effect.
3. **Whether they are revised if original interventions are not successful.**
   - If repeat measures do not yield improvements, explain how problem solving and data analysis was performed to identify possible causes.
   - Identify revised interventions and explain how they were planned, developed, and implemented.
4. **Whether they are standardized and monitored if interventions are successful.**
   - If study indicators demonstrated improvement, it should be documented that the interventions were then standardized and monitored.

Describe interventions:

Baseline to Remeasurement 1:

Remeasurement 1 to Remeasurement 2:

Remeasurement 2 to Remeasurement 3:

H. Activity VIIIa. Analyze data: Describe the data analysis process done in accordance with the data analysis plan and any ad hoc analyses (e.g. data mining) done on the selected clinical or nonclinical study indicators. Include the statistical analysis techniques used and *p* values.

Describe data analysis and interpretation ensuring that:

1. Data analysis was conducted according to the data analysis plan in the study design.

- Conduct data analysis according to the data analysis plan.
- The data analysis plan should describe in narrative form how data analysis will be conducted. Essential components of a data analysis plan include: how the study indicator rate or mean will be calculated, how the study indicator rate or mean will be compared to a goal or benchmark, and what statistical test will be used to compare study indicator rates or means between measurement periods. If subgroup analysis will be conducted, the data analysis plan should identify those sub groups and what comparisons will be done as well as what statistical testing will be done on the subgroup level.

2. Allows for the generalization of results to the study population if a sample was selected. (Critical Element)

- Ensure the statistical techniques utilized allow for the results to be generalizable to the study population (if a sample was selected).

3. Factors that threaten internal or external validity were identified.

- Identify factors that threaten internal or external validity of the findings.
- Examples of factors would be a change in demographic population, acquiring another health plan's members, or a change in health plan staff.
- If there are no identified factors, this information should be stated in the text of the QIP Summary Form.

4. An interpretation of findings was included.

- Include analysis and an interpretation of the study data.
- Ensure all the data analysis plan components are included in the interpretation.
- Include an interpretation of the statistical testing.

H. Activity VIIIa. Analyze data: Describe the data analysis process done in accordance with the data analysis plan and any ad hoc analyses (e.g. data mining) done on the selected clinical or nonclinical study indicators. Include the statistical analysis techniques used and *p* values.

5. The data analysis was presented in a way that provides accurate, clear, and easily understood information. (Critical Element)

- Present the QIP results in a table or graph with measurement periods, results, and benchmarks clearly identified.

6. Initial measurement and remeasurement of study indicators were identified.

- Identify Baseline measurement and remeasurement for all study indicators.

7. Statistical differences between initial measurement and remeasurement were identified.

- Perform statistical testing between measurements (e.g., a Chi-square test, *t* test or *z* test for proportions, or Fisher's Exact test)
- Perform all statistical testing using a two-tailed approach to calculate the *p* value. Please include the statistical test used, the test statistic, and the *p* value to four decimal places (i.e., 0.0235). If the *p* value is less than 0.0001, please indicate the *p* value as ≤ 0.0001.
- Discuss statistical differences (using specific *p* values) including the interpretation of the *p* value.

8. Factors that affect the ability to compare the initial measurement with remeasurement were identified.

- Identify factors that affect the ability to compare measurements.
- An example would be a change in the methodology.
- If none – QIP should document this.

9. Includes an interpretation of the extent to which the study was successful.

- The QIP should include an overall interpretation of the extent to which the QIP was successful, as well as follow-up activities planned as a result of the interpretation. Even if the QIP did not show improvement in the study indicator results, the QIP may have experienced success in other areas that it could share. The interpretation should discuss lessons learned and follow-up activities.
- Include in the interpretation of findings the extent to which the QIP was successful and follow-up activities planned as a result.

H. Activity VIIIa. Analyze data: Describe the data analysis process done in accordance with the data analysis plan and any ad hoc analyses (e.g. data mining) done on the selected clinical or nonclinical study indicators. Include the statistical analysis techniques used and *p* values.
Describe the data analysis process (include the data analysis plan): **Baseline Measurement:** **Baseline to Remeasurement 1:** **Remeasurement 1 to Remeasurement 2:** **Remeasurement 2 to Remeasurement 3:**

H. Activity VIIIb. Interpret study results: Describe the results of the statistical analysis, interpret the findings, and compare and discuss results/changes from measurement period to measurement period. Discuss the successfulness of the study and indicate follow-up activities. Identify any factors that could influence the measurement or validity of the findings.
Interpretation of study results (address factors that threaten the internal or external validity of the findings for each measurement period): **Baseline Measurement:** **Baseline to Remeasurement 1:** **Remeasurement 1 to Remeasurement 2:** **Remeasurement 2 to Remeasurement 3:**

I. Activity IX: Plan for "real" improvement. Enter results for each study indicator, including benchmarks and statistical testing with complete *p* values, and statistical significance.

There is evidence of "real" improvement based on the following:

1. Remeasurement methodology is the same as the Baseline methodology.

- Describe the use of the same methodology for Baseline and remeasurements.
- If there was a change in methodology, the issue, impact, and resolution should be discussed to justify the needed changes.

2. Documented improvement in processes or outcomes of care.

- All study indicators should demonstrate improvement.
- Documentation should include how intervention(s) were successful in affecting system wide processes or health care outcomes.

3. Improvement appeared to be the result of planned intervention(s).

- Explain how the improvement in the study indicator(s) results was related to the intervention(s).

4. Statistical evidence that observed improvement is true improvement.

- Calculate and report the degree to which the intervention(s) were statistically significant using specific *p* values.

I. Activity IX: Plan for "real" improvement. Enter results for each study indicator, including benchmarks and statistical testing with complete *p* values, and statistical significance.

Quantifiable Measure No. 1: Enter the title of study indicator.

Time Period Measurement Covers	Baseline Project Indicator Measurement	Numerator	Denominator	Rate or Results	Industry Benchmark	Statistical Test Significance and *p* value
	Baseline:					
	Remeasurement 1					
	Remeasurement 2					
	Remeasurement 3					
	Remeasurement 4					
	Remeasurement 5					

Describe any demonstration of meaningful change in performance observed from Baseline and each measurement period (e.g. Baseline to Remeasurement 1, Remeasurement 1 to Remeasurement 2, or Baseline to final remeasurement) for each study indicator.

Quantifiable Measure No. 2: Enter the title of study indicator.

Time Period Measurement Covers	Baseline Project Indicator Measurement	Numerator	Denominator	Rate or Results	Industry Benchmark	Statistical Test Significance and *p* value
	Baseline:					
	Remeasurement 1					
	Remeasurement 2					
	Remeasurement 3					
	Remeasurement 4					
	Remeasurement 5					

Describe any demonstration of meaningful change in performance observed from Baseline and each measurement period (e.g. Baseline to Remeasurement 1, Remeasurement 1 to Remeasurement 2, or Baseline to final remeasurement) for each study indicator.

I. Activity IX: Plan for "real" improvement. Enter results for each study indicator, including benchmarks and statistical testing with complete *p* values, and statistical significance.

Quantifiable Measure No. 3: Enter the title of study indicator.

Time Period Measurement Covers	Baseline Project Indicator Measurement	Numerator	Denominator	Rate or Results	Industry Benchmark	Statistical Test Significance and *p* value
	Baseline:					
	Remeasurement 1					
	Remeasurement 2					
	Remeasurement 3					
	Remeasurement 4					
	Remeasurement 5					

Describe any demonstration of meaningful change in performance observed from Baseline and each measurement period (e.g. Baseline to Remeasurement 1, Remeasurement 1 to Remeasurement 2, or Baseline to final remeasurement) for each study indicator.

J. Activity X: Achieve sustained improvement. Describe any demonstrated improvement through repeated measurements over comparable time periods. Discuss any random, year-to-year variations, population changes, sampling errors, or statistically significant declines that may have occurred during the remeasurement process

Sustained improvement:

Describe any sustained improvements that are demonstrated by repeated measurements over time, and discuss any potential causes for random year-to-year variation.

1. Repeated measurements over comparable time periods demonstrate sustained improvement, or that a decline in improvement is not statistically significant.

- Demonstrated improvement in all of the study indicators should be explained.
- If there is a decline in improvement, perform statistical testing to determine if decline was statistically significant.
- This activity is not assessed until a Baseline and a minimum of two annual measurements have been completed.

Appendix B. California Medi-Cal Managed Care Program
Quality Improvement Projects
QIP Summary Form Completion Instructions (Multi-County)

Each section provides guidance based on CMS' protocols for how to document the QIP. HSAG provides specific comments for individual plans during the QIP evaluation and validation process.

DEMOGRAPHIC INFORMATION	
Plan Name: **<Full Name>**	
Study Leader Name: _____	Title: _____
Telephone Number: _____	E-Mail Address: _____
Name of Project/Study: ***<QIP Topic>***	
County/Counties Reported: _____	
Type of Study: ☐ Clinical ☐ Nonclinical ☐ HEDIS ☐ IQIP ☐ SGC ☐ Statewide Collaborative	**Section to be completed by HSAG** _____ Year 1 Validation _____ Initial Submission _____ Resubmission _____ Year 2 Validation _____ Initial Submission _____ Resubmission _____ Year 3 Validation _____ Initial Submission _____ Resubmission
Date of Study: _____ to _____	_____ Baseline Assessment _____ Remeasurement 2 _____ Remeasurement 1 _____ Remeasurement 3
Type of Delivery System: MCP	
Number of Medi-Cal Members in Plan _____ Number of Medi-Cal Members in Study _____	Year 1 validated through Activity _____ Year 2 validated through Activity _____ Year 3 validated through Activity _____
Type of Submission: ☐ Proposal ☐ Annual Submission ☐ Resubmission Submission Date: _____	

A. Activity I: Select the study topic. QIP topics should target improvement in relevant areas of services and reflect the population in terms of demographic characteristics, prevalence of disease, and the potential consequences (risks) of disease. Topics may be derived from utilization data (ICD-9 or CPT coding data related to diagnoses and procedures; NDC codes for medications; HCPCS codes for medications, medical supplies, and medical equipment; adverse events; admissions; readmissions; etc.); grievances and appeals data; survey data; provider access or appointment availability data; member characteristics data such as race/ethnicity/language; other fee-for-service data; or local or national data related to Medicaid risk populations. The goal of the project should be to improve processes and outcomes of health care or services in order to have a potentially significant impact on member health, functional status, or satisfaction. The topic may be specified by the state Medicaid agency or CMS, or it may be based on input from members. Over time, topics must cover a broad spectrum of key aspects of member care and services, including clinical and nonclinical areas, and should include all enrolled populations (i.e., certain subsets of members should not be consistently excluded from studies).

Study topic:
Clearly state the study topic. Specify if the topic was assigned by the State. Explain how the study topic was selected, addressing the following required HSAG evaluation elements:

1. Reflects high-volume or high-risk conditions.

- The narrative should describe how the study topic reflects a high-volume or high-risk condition or service for the plan.
- If the study topic was selected by the California DHCS, this must be specified in the QIP Summary Form.

2. Is selected following collection and analysis of data.

- Provide plan-specific data collection and analysis to support the selection of the study topic.
- If no plan-specific data were available, provide rationale for why it was not included.
- Plans need to document all counties covered and provide county-specific background data (i.e., the county-specific population and its characteristics).

3. Addresses a broad spectrum of care and services.

- For clinical focus areas, the study topic should include prevention and care of acute and chronic conditions and high-volume/high-risk services.
- For non-clinical focus areas, continuity of care should be addressed in a manner in which care was provided from multiple providers across multiple episodes of care.
- Additionally, topics such as member satisfaction or the over utilization of emergency room services might also be appropriate.

A. Activity I: Select the study topic. QIP topics should target improvement in relevant areas of services and reflect the population in terms of demographic characteristics, prevalence of disease, and the potential consequences (risks) of disease. Topics may be derived from utilization data (ICD-9 or CPT coding data related to diagnoses and procedures; NDC codes for medications; HCPCS codes for medications, medical supplies, and medical equipment; adverse events; admissions; readmissions; etc.); grievances and appeals data; survey data; provider access or appointment availability data; member characteristics data such as race/ethnicity/language; other fee-for-service data; or local or national data related to Medicaid risk populations. The goal of the project should be to improve processes and outcomes of health care or services in order to have a potentially significant impact on member health, functional status, or satisfaction. The topic may be specified by the state Medicaid agency or CMS, or it may be based on input from members. Over time, topics must cover a broad spectrum of key aspects of member care and services, including clinical and nonclinical areas, and should include all enrolled populations (i.e., certain subsets of members should not be consistently excluded from studies).

4. Includes all eligible populations that meet the study criteria.

- Explain if all eligible populations that met the study criteria were included in the study.
- The eligible population for the QIP should be described in Activity I.
- If the eligible population was selected by the California DHCS, there must be reference to that in the QIP Summary Form.

5. Does not exclude members with special health care needs.

- Include a statement about the inclusion or exclusion of members with special health care needs.
- If members with special health care needs were excluded from the study, explain why.

6. Has the potential to affect member health, functional status, or satisfaction. (Critical Element)

- The narrative should explain how the study topic has the potential to affect member health, functional status, or satisfaction.
- The link between the study topic and outcomes of care should be explained in Activity I.

B. Activity II: Define the study question(s). Stating the question(s) helps maintain the focus of the QIP and sets the framework for data collection, analysis, and interpretation.

Study question:

Enter written QIP study question(s) here. Ensure the study question(s) addresses the following HSAG evaluation elements:

1. States the problem to be studied in simple terms. (Critical Element)

- Per CMS' protocol, the study question(s) should be stated in the format, "Does doing X result in Y?"
- Define terms used in the study question(s) that might not be clear.

2. Is answerable. (Critical Element)

- The study question(s) must be answerable through the proposed data collection methodology and study indicator(s) provided.

C. Activity III: Select the study indicator(s). A study indicator is a quantitative or qualitative characteristic or variable that reflects a discrete event (e.g., an older adult has not received an influenza vaccination in the last 12 months) or a status (e.g., a member's blood pressure is/is not below a specified level) that is to be measured. The selected indicators should track performance or improvement over time. The indicators should be objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research.

Study indicators:

List any details or background information about the indicator(s) and how they were selected.

Enter the study indicator(s) in the table for Activity III, ensuring that, at a minimum:

1. The indicator(s) are well-defined, objective, and measurable. **(Critical Element)**

- Provide study indicator(s) that are objective and measurable. Complete descriptions of the numerators and denominators should be provided.
- Define terms used in the indicator(s). Include any codes used to define numerator events.
- Provide the description/rationale for each study indicator(s).
- Include all starting and ending dates for all measurement periods.

2. Are based on current, evidence-based practice guidelines, pertinent peer-reviewed literature, or consensus expert panels.

- Study indicator(s) should be based on current clinical practice guidelines or health services research, and these sources should be specified in the QIP documentation.
- If the study indicator(s) is not based on any of the above, the documentation should include this.
- If the study indicator(s) was provided by the State, the documentation in Activity III should include this.

3. The indicator(s) allow for the study question to be answered. (Critical Element)

- The study indicator(s) should provide data to answer the reported study question(s).
- The study indicator(s) and study question(s) should align.

C. Activity III: Select the study indicator(s). A study indicator is a quantitative or qualitative characteristic or variable that reflects a discrete event (e.g., an older adult has not received an influenza vaccination in the last 12 months) or a status (e.g., a member's blood pressure is/is not below a specified level) that is to be measured. The selected indicators should track performance or improvement over time. The indicators should be objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research.

4. The indicator(s) measure changes (outcomes) in health or functional status, member satisfaction, or valid process alternatives.

- The study indicator(s) must objectively measure member outcomes such as health, functional status, and/or member satisfaction or valid process alternatives.

5. The indicator(s) have available data that can be collected on each indicator. (Critical Element)

- Data should be available through administrative sources, medical records, surveys, or other readily available sources.

6. The study indicators are nationally recognized measures, such as HEDIS technical specifications, when appropriate.

- When appropriate, nationally recognized measures, such as HEDIS, should be used.
- If the study indicator(s) are nationally recognized measures, this should be explained in the QIP documentation. The year of the specifications should also be included, and updated annually, if appropriate.

7. Include the basis on which indicator(s) was adopted, if internally developed.

- If the study indicator(s) were internally developed, the rationale and explanation why each study indicator(s) was chosen for the QIP should be provided in the QIP Summary Form.

C. Activity III: Select the study indicator(s). A study indicator is a quantitative or qualitative characteristic or variable that reflects a discrete event (e.g., an older adult has not received an influenza vaccination in the last 12 months) or a status (e.g., a member's blood pressure is/is not below a specified level) that is to be measured. The selected indicators should track performance or improvement over time. The indicators should be objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research.	
Study Indicator 1	**Describe the rationale for selection of the study indicator:**
Numerator: (no numeric value)	
Denominator: (no numeric value)	
Baseline Measurement Period	
Baseline Goal	
Remeasurement 1 Period	
Remeasurement 2 Period	
Benchmark	
Source of Benchmark	
Study Indicator 2	**Describe the rationale for selection of the study indicator:**
Numerator: (no numeric value)	
Denominator: (no numeric value)	
Baseline Measurement Period	
Baseline Goal	
Remeasurement 1 Period	
Remeasurement 2 Period	
Benchmark	
Source of Benchmark	

C. Activity III: Select the study indicator(s). A study indicator is a quantitative or qualitative characteristic or variable that reflects a discrete event (e.g., an older adult has not received an influenza vaccination in the last 12 months) or a status (e.g., a member's blood pressure is/is not below a specified level) that is to be measured. The selected indicators should track performance or improvement over time. The indicators should be objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research.

Study Indicator 3	**Describe the rationale for selection of the study indicator:**
Numerator: (no numeric value)	
Denominator: (no numeric value)	
Baseline Measurement Period	
Baseline Goal	
Remeasurement 1 Period	
Remeasurement 2 Period	
Benchmark	
Source of Benchmark	

Use this area to provide additional information. Discuss the guidelines used and the basis for each study indicator.

D. Activity IV: Use a representative and generalizable study population. The selected topic should represent the entire eligible population of Medicaid members with systemwide measurement and improvement efforts to which the study indicators apply. Once the population is identified, a decision must be made whether or not to review data for the entire population or a sample of that population. The length of members' enrollment needs to be defined to meet the study population criteria.

Study population:

Describe the population and methods for identifying the study population. Identify the study population, addressing the following HSAG evaluation elements:

1. The study population is accurately and completely defined. (Critical Element)

- Clearly define inclusion, exclusion, and diagnosis criteria.
- Include a list of diagnosis codes or system codes used to identify members.
- Include any anchor dates used to identify age criteria.

2. The study population includes requirements for the length of a member's enrollment in the plan.

- Define continuous enrollment, new enrollment, and allowable gaps in enrollment.
- Any dates used to identify continuous enrollment criteria should be included.

3. The study population captures all members to whom the study question applies. (Critical Element)

- The eligible population should include all members to whom the study question applies.

E. Activity V: Use sound sampling techniques. If sampling is used to select members of the study, proper sampling techniques are necessary to provide valid and reliable information on the quality of care provided. The true prevalence or incidence rate for the event in the population may not be known the first time a topic is studied.

Sampling methods:

Enter sampling techniques used to select members for the study. Make sure that the responses address all HSAG evaluation elements below. If the entire eligible population was used, document this in Activity V of the QIP Summary Form.

*** Plans should provide sampling methodology for each county, if applicable.**

Use the entire population, or

1. Consider and specify the true or estimated frequency of occurrence.

- The true or estimated frequency of occurrence should be considered in the sampling equation.

2. Identify the sample size.

3. Specify the confidence level to be used.

4. Specify the acceptable margin of error.

5. Ensure a representative sample of the eligible population. (Critical Element)

- Representative sampling techniques should be used to ensure generalizable information. For example, include the process used to select the study sample.
- If NCQA certified software is used to select the sample, include the certified software seal.

6. Are in accordance with generally accepted principles of research design and statistical analysis.

- Valid sampling techniques should be used for all study indicators, which can be replicated using the reported results.

County	Measure	Sample Error and Confidence Level	Sample Size	Population	Method for Determining Size (*Describe*)	Sampling Method (*Describe*)

F. Activity VIa: Reliably collect data. Data collection must ensure that the data collected on QIP indicators are valid and reliable. Validity is an indication of the accuracy of the information obtained. Reliability is an indication of the repeatability or reproducibility of a measurement.

Data Collection:

Enter data collection techniques. Make sure that the responses address all HSAG evaluation elements below:

*** Plans should provide data collection procedures used at the county level, if applicable.**

1. Identification of data elements to be collected.

- Documentation should include clear definitions of the data elements to be collected.
- If using HEDIS, submit the HEDIS Compliance Final Audit Report.

2. Identification of specified sources of data.

- The sources of data should be clearly specified.

3. A defined and systematic process for collecting baseline and remeasurement data.

- A systematic method for data collection should be specified.
- If an NCQA vendor was used to collect data, include the vendor's name.

4. A timeline for the collection of baseline and remeasurement data.

- The timeline should include both starting and ending dates for baseline and all measurement periods.

IF MANUAL DATA COLLECTION WAS USED:

5. Qualified staff and personnel to abstract manual data.

- The relevant education, experience, and training of all manual data collection staff should be described in the QIP Summary Form.

6. A manual data collection tool that ensures consistent and accurate collection of data according to indicator specifications. (Critical Element)

- Include the manual data collection tool with the QIP submission.
- For mailed surveys, include the cover letter and survey.
- For telephone surveys, include the script as well as the monitoring and training process for the telephone survey staff.

F. Activity VIa: Reliably collect data. Data collection must ensure that the data collected on QIP indicators are valid and reliable. Validity is an indication of the accuracy of the information obtained. Reliability is an indication of the repeatability or reproducibility of a measurement.

7. A manual data collection tool that supports interrater reliability (IRR).

- Include a discussion of the IRR process.

8. Clear and concise written instructions for completing the manual data collection tool.

- Written instructions for the manual data collection tool should be clearly and succinctly written and included with the QIP submission.

9. An overview of the study in written instructions.

- A brief statement about the purpose of the study should be included in the written instructions for the manual data collection tool.

IF ADMINISTRATIVE DATA WERE COLLECTED:

10. Administrative data collection algorithms/flow charts that show activities in the production of indicators.

- Documentation should include a systematic process of an ordered sequence of steps. Each step depends on the outcome of the previous step. This can be defined in a narrative, or with algorithms/flow charts.

11. An estimated degree of administrative data completeness.

- The estimated degree of administrative data completeness and a description of the process used for that determination should be included.

F. Activity VIa: Reliably collect data. Data collection must ensure that the data collected on QIP indicators are valid and reliable. Validity is an indication of the accuracy of the information obtained. Reliability is an indication of the repeatability or reproducibility of a measurement.

Data Sources

[ ] Hybrid (medical/treatment records and administrative)

[ ] Medical/Treatment Record Abstraction

Record Type

[ ] Outpatient
[ ] Inpatient
[ ] Other _____

Other Requirements

[ ] Data collection tool attached
[ ] Data collection instructions attached
[ ] Summary of data collection training attached
[ ] IRR process and results attached

[ ] Other data

Description of data collection staff (include training, experience, and qualifications):

[ ] Administrative Data

Data Source

[ ] Programmed pull from claims/encounters
[ ] Complaint/appeal
[ ] Pharmacy data
[ ] Telephone service data /call center data
[ ] Appointment/access data
[ ] Delegated entity/vendor data _____
[ ] Other _____

Other Requirements

[ ] Data completeness assessment attached
[ ] Coding verification process attached

[ ] Survey Data

Fielding Method

[ ] Personal interview
[ ] Mail
[ ] Phone with CATI script
[ ] Phone with IVR
[ ] Internet
[ ] Other _____

Other Requirements

[ ] Number of waves _____
[ ] Response rate _____
[ ] Incentives used _____

F. Activity VIb: Determine the data collection cycle.	**Determine the data analysis cycle.**
[ ] Once a year [ ] Twice a year [ ] Once a season [ ] Once a quarter [ ] Once a month [ ] Once a week [ ] Once a day [ ] Continuous [ ] Other (list and describe): _____ _____ _____	[ ] Once a year [ ] Once a season [ ] Once a quarter [ ] Once a month [ ] Continuous [ ] Other (list and describe): _____ _____ _____ _____ _____

F. Activity VIc. Data analysis plan and other pertinent methodological features.

Estimated degree of administrative data completeness: _____ percent.

Describe the process used to determine data completeness and accuracy.

Supporting documentation:

_____
_____
_____

G. Activity VIIa: Implement intervention and improvement strategies. (Interventions for improvement as a result of analysis). List chronologically the interventions that have had the most impact on improving the measure. Describe only the interventions and provide quantitative details whenever possible (e.g., "Hired four customer service representatives" as opposed to "Hired customer service representatives"). Do not include intervention planning activities.

County	Date Implemented (MMYY)	Check if Ongoing	Interventions	Barriers That Interventions Address
***If interventions were implemented across all counties, plans can enter "All" in the County column.**				

G. Activity VIIb: Implement intervention and improvement strategies. Real, sustained improvements in care result from a continuous cycle of measuring and analyzing performance, as well as, developing and implementing systemwide improvements in care. Describe interventions designed to change behavior at an institutional, practitioner, or member level.

Interventions:

Describe interventions/improvement strategies for each measurement period. The interventions/improvement strategies should address the following HSAG required evaluation elements:

1. **Whether they are related to causes/barriers identified through data analysis and quality improvement (QI) processes. (Critical Element)**
   - Describe the causal/barrier analysis process used and explain how the intervention(s) were related to causes/barriers identified through data analysis and quality improvement processes.
2. **Whether they are system changes that are likely to induce permanent change.**
   - Select and include in the documentation, system interventions that will likely have a permanent effect.
3. **Whether they are revised if original interventions are not successful.**
   - If repeat measures do not yield improvements, explain how problem solving and data analysis was performed to identify possible causes.
   - Identify revised interventions and explain how they were planned, developed, and implemented.
4. **Whether they are standardized and monitored if interventions are successful.**
   - If study indicators demonstrated improvement, it should be documented that the interventions were then standardized and monitored.

Describe interventions:

Baseline to Remeasurement 1:
County Name:
County Name:
County Name:
County Name:
County Name:

G. Activity VIIb: Implement intervention and improvement strategies. Real, sustained improvements in care result from a continuous cycle of measuring and analyzing performance, as well as, developing and implementing systemwide improvements in care. Describe interventions designed to change behavior at an institutional, practitioner, or member level.

County Name:
County Name:
County Name:
County Name:

Remeasurement 1 to Remeasurement 2:

County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:

Remeasurement 2 to Remeasurement 3:

County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:

H. Activity VIIIa. Analyze data: Describe the data analysis process done in accordance with the data analysis plan and any ad hoc analyses (e.g. data mining) done on the selected clinical or nonclinical study indicators. Include the statistical analysis techniques used and *p* values.

Describe data analysis and interpretation ensuring that:

1. Data analysis was conducted according to the data analysis plan in the study design.

- Conduct data analysis according to the data analysis plan.
- The data analysis plan should describe in narrative form how data analysis will be conducted. Essential components of a data analysis plan include: how the study indicator rate or mean will be calculated, how the study indicator rate or mean will be compared to a goal or benchmark, and what statistical test will be used to compare study indicator rates or means between measurement periods. If subgroup analysis will be conducted, the data analysis plan should identify those sub groups and what comparisons will be done as well as what statistical testing will be done on the subgroup level.

2. Allows for the generalization of results to the study population if a sample was selected. (Critical Element)

- Ensure the statistical techniques utilized allow for the results to be generalizable to the study population (if a sample was selected).

3. Factors that threaten internal or external validity were identified.

- Identify factors that threaten the internal or external validity of the findings for each county.
- Examples of factors would be a change in demographic population, acquiring another health plan's members, or a change in health plan staff.
- If there are no identified factors, this information should be stated in the text of the QIP Summary Form.

4. An interpretation of findings was included.

- Include analysis and an interpretation of the study data.
- Ensure all the data analysis plan components are included in the interpretation.
- Include an interpretation of the statistical testing.

H. Activity VIIIa. Analyze data: Describe the data analysis process done in accordance with the data analysis plan and any ad hoc analyses (e.g. data mining) done on the selected clinical or nonclinical study indicators. Include the statistical analysis techniques used and *p* values.

5. The data analysis was presented in a way that provides accurate, clear, and easily understood information. (Critical Element)

- Present the QIP results in a table or graph with measurement periods, results, and benchmarks clearly identified.

6. Initial measurement and remeasurement of study indicators were identified.

- Identify baseline measurement and remeasurement for all study indicators.

7. Statistical differences between initial measurement and remeasurement were identified.

- Identify statistical differences between measurements for each county, if applicable.
- Perform statistical testing between measurements (e.g., a Chi-square test, *t* test or *z* test for proportions, or Fisher's Exact test)
- Perform all statistical testing using a two-tailed approach to calculate the *p* value. Please include the statistical test used, the test statistic, and the *p* value to four decimal places (i.e. 0.0235). If the *p* value is less than 0.0001, please indicate the *p* value as ≤ 0.0001.
- Discuss statistical differences (using specific *p* values) including the interpretation of the *p* value.

8. Factors that affect the ability to compare the initial measurement with remeasurement were identified.

- Identify factors that affect the ability to compare measurements for each county.
- An example would be a change in the methodology.
- If none – QIP should document this.

9. Includes an interpretation of the extent to which the study was successful.

- The QIP should include an overall interpretation of the extent to which the QIP was successful, as well as follow-up activities planned as a result of the interpretation. Even if the QIP did not show improvement in the study indicator results, the QIP may have experienced success in other areas that it could share. The interpretation should discuss lessons learned and follow-up activities.
- Include in the interpretation of findings the extent to which the QIP was successful and follow-up activities planned as a result.

H. Activity VIIIa. Analyze data: Describe the data analysis process done in accordance with the data analysis plan and any ad hoc analyses (e.g. data mining) done on the selected clinical or nonclinical study indicators. Include the statistical analysis techniques used and *p* values.

Describe the data analysis process (include the data analysis plan):

Baseline Measurement:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:

Baseline to Remeasurement 1:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:

H. Activity VIIIa. Analyze data: Describe the data analysis process done in accordance with the data analysis plan and any ad hoc analyses (e.g. data mining) done on the selected clinical or nonclinical study indicators. Include the statistical analysis techniques used and *p* values.

Remeasurement 1 to Remeasurement 2:

County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:

Remeasurement 2 to Remeasurement 3:

County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:

H. Activity VIIIb. Interpret study results: Describe the results of the statistical analysis, interpret the findings, and compare and discuss results/changes from measurement period to measurement period. Discuss the successfulness of the study and indicate follow-up activities. Identify any factors that could influence the measurement or validity of the findings.

Interpretation of study results (address factors that threaten the internal or external validity of the findings for each measurement period):

Baseline Measurement:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:

Baseline to Remeasurement 1:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:

H. Activity VIIIb. Interpret study results: Describe the results of the statistical analysis, interpret the findings, and compare and discuss results/changes from measurement period to measurement period. Discuss the successfulness of the study and indicate follow-up activities. Identify any factors that could influence the measurement or validity of the findings.

Remeasurement 1 to Remeasurement 2:

County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:

Remeasurement 2 to Remeasurement 3:

County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:

I. Activity IX: Plan for "real" improvement. Enter results for each study indicator, including benchmarks and statistical testing with complete *p* values, and statistical significance.

There is evidence of "real" improvement based on the following:

1. Remeasurement methodology is the same as the baseline methodology.

- Describe the use of the same methodology for baseline and remeasurements.
- If there was a change in methodology, the issue, impact, and resolution should be discussed to justify the needed changes.

2. Documented improvement in processes or outcomes of care.

- All study indicators should demonstrate improvement.
- Documentation should include how intervention(s) were successful in affecting system wide processes or health care outcomes.

3. Improvement appeared to be the result of planned intervention(s).

- Explain how the improvement in the study indicator(s) results was related to the intervention(s).

4. Statistical evidence that observed improvement is true improvement.

- Calculate and report the degree to which the intervention(s) were statistically significant using specific *p* values.

I. Activity IX: Plan for "real" improvement. Enter results for each study indicator, including benchmarks and statistical testing with complete *p* values, and statistical significance.

Quantifiable Measure No. 1: Enter the title of study indicator.

Time Period Measurement Covers	Baseline Project Indicator Measurement	Numerator	Denominator	Rate or Results	Industry Benchmark	Statistical Test Significance and *p* value
	Baseline					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	Remeasurement 1					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					

I. Activity IX: Plan for "real" improvement. Enter results for each study indicator, including benchmarks and statistical testing with complete *p* values, and statistical significance.

Quantifiable Measure No. 1: Enter the title of study indicator.

Time Period Measurement Covers	Baseline Project Indicator Measurement	Numerator	Denominator	Rate or Results	Industry Benchmark	Statistical Test Significance and *p* value
	Remeasurement 2					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					

Describe any demonstration of meaningful change in performance observed from baseline and each measurement period (e.g., baseline to Remeasurement 1, Remeasurement 1 to Remeasurement 2, or baseline to final remeasurement) for each study indicator:

I. Activity IX: Plan for "real" improvement. Enter results for each study indicator, including benchmarks and statistical testing with complete p values, and statistical significance.

Quantifiable Measure 2:

Time Period Measurement Covers	Baseline Project Indicator Measurement	Numerator	Denominator	Rate or Results	Industry Benchmark	Statistical Test Significance and *p* value
	Baseline					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	Remeasurement 1					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					

I. Activity IX: Plan for "real" improvement. Enter results for each study indicator, including benchmarks and statistical testing with complete p values, and statistical significance.

Quantifiable Measure 2:

Time Period Measurement Covers	Baseline Project Indicator Measurement	Numerator	Denominator	Rate or Results	Industry Benchmark	Statistical Test Significance and *p* value
	Remeasurement 2					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					

Describe any demonstration of meaningful change in performance observed from baseline and each measurement period (e.g., baseline to Remeasurement 1, Remeasurement 1 to Remeasurement 2, or baseline to final remeasurement) for each study indicator:

I. Activity IX: Plan for "real" improvement. Enter results for each study indicator, including benchmarks and statistical testing with complete p values, and statistical significance.

Quantifiable Measure 3:

Time Period Measurement Covers	Baseline Project Indicator Measurement	Numerator	Denominator	Rate or Results	Industry Benchmark	Statistical Test Significance and *p* value
	Baseline					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	Remeasurement 1					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					

I. Activity IX: Plan for "real" improvement. Enter results for each study indicator, including benchmarks and statistical testing with complete p values, and statistical significance.

Quantifiable Measure 3:

Time Period Measurement Covers	Baseline Project Indicator Measurement	Numerator	Denominator	Rate or Results	Industry Benchmark	Statistical Test Significance and *p* value
	Remeasurement 2					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					
	County Name:					

Describe any demonstration of meaningful change in performance observed from baseline and each measurement period (e.g., baseline to Remeasurement 1, Remeasurement 1 to Remeasurement 2, or baseline to final remeasurement) for each study indicator:

J. Activity X: Achieve sustained improvement. Describe any demonstrated improvement through repeated measurements over comparable time periods. Discuss any random, year-to-year variations, population changes, sampling errors, or statistically significant declines that may have occurred during the remeasurement process

Sustained improvement:

Describe any sustained improvements that are demonstrated by repeated measurements over time, and discuss any potential causes for random year-to-year variation.

1. Repeated measurements over comparable time periods demonstrate sustained improvement, or that a decline in improvement is not statistically significant.

- Demonstrated improvement in all of the study indicators should be explained.
- If there is a decline in improvement, perform statistical testing to determine if decline was statistically significant.
- This activity is not assessed until a baseline and a minimum of two annual measurements have been completed.

County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:
County Name:

Appendix C. California Medi-Cal Managed Care Program
QIP Validation Tool:
<QIP Topic>
for <Full Name>

DEMOGRAPHIC INFORMATION	
Plan Name: **<Full Name>**	
Study Leader Name: _____	Title: _____
Telephone Number: _____	E-mail Address: _____
Name of Project/Study: **<QIP Topic>**	
County/Counties Reported: _____	
Type of Study: ☐ Clinical ☐ Nonclinical ☐ HEDIS ☐ IQIP ☐ SGC ☐ Statewide Collaborative	**Section to be completed by HSAG** _____ Year 1 Validation _____ Initial Submission _____ Resubmission _____ Year 2 Validation _____ Initial Submission _____ Resubmission _____ Year 3 Validation _____ Initial Submission _____ Resubmission
Date of Study: _____ to _____	
Type of Delivery System : MCP	
Number of Medi-Cal Members in Plan: _____ Number of Medi-Cal Members in Study: _____	_____ Baseline Assessment _____ Remeasurement 1 _____ Remeasurement 2 _____ Remeasurement 3
Type of Submission: ☐ Proposal ☐ Annual Submission ☐ Resubmission Submission Date: _____	Year 1 validated through Activity _____ Year 2 validated through Activity _____ Year 3 validated through Activity _____

EVALUATION ELEMENTS		SCORING	COMMENTS
Quality Improvement Project/Health Care Study Evaluation			
I.	**Review the Selected Study Topic(s): Topics selected for the study should reflect the Medi-Cal enrolled population in terms of demographic characteristics, prevalence of disease, and the potential consequences (risks) of disease. Topics could also address the need for a specific service. The goal of the project should be to improve processes and outcomes of health care. The topic may be specified by California DHCS or based on input from Medi-Cal members. The study topic:**		
—	1. Reflects high-volume or high-risk conditions.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
—	2. Is selected following collection and analysis of data. ***NA*** is not applicable to this element for scoring.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
—	3. Addresses a broad spectrum of care and services. The score for this element will be ***Met*** **or** ***Not Met*****.**	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
—	4. Includes all eligible populations that meet the study criteria. ***NA*** is not applicable to this element for scoring.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
—	5. Does not exclude members with special health care needs. The score for this element will be ***Met*** **or** ***Not Met*****.**	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	

EVALUATION ELEMENTS		SCORING	COMMENTS
Quality Improvement Project/Health Care Study Evaluation			
I.	**Review the Selected Study Topic(s): Topics selected for the study should reflect the Medi-Cal enrolled population in terms of demographic characteristics, prevalence of disease, and the potential consequences (risks) of disease. Topics could also address the need for a specific service. The goal of the project should be to improve processes and outcomes of health care. The topic may be specified by California DHCS or based on input from Medi-Cal members. The study topic:**		
C*	6. Has the potential to affect member health, functional status, or satisfaction. The score for this element will be ***Met* or *Not Met*.**	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	

Results for Activity I

Total Evaluation Elements				
Total Evaluation Elements**	*Met*	*Partially Met*	*Not Met*	*NA*
6	0	0	0	0

Critical Elements				
Critical Elements***	*Met*	*Partially Met*	*Not Met*	*NA*
1	0	0	0	0

* "C" in this column denotes a *critical* evaluation element.

** This is the total number of *all* evaluation elements for this review activity.

*** This is the total number of *critical* evaluation elements for this review activity.

EVALUATION ELEMENTS		SCORING	COMMENTS
Quality Improvement Project/Health Care Study Evaluation			
II.	**Review the Study Question(s): Stating the study question(s) helps maintain the focus of the QIP and sets the framework for data collection, analysis, and interpretation. The study question:**		
C	1. States the problem to be studied in simple terms. ***NA*** is not applicable to this element for scoring.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
C	2. Is answerable. ***NA*** is not applicable to this element for scoring.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	

Results for Activity II

Total Evaluation Elements				
Total Evaluation Elements	*Met*	*Partially Met*	*Not Met*	*NA*
2	0	0	0	0

Critical Elements				
Critical Elements	*Met*	*Partially Met*	*Not Met*	*NA*
2	0	0	0	0

EVALUATION ELEMENTS		SCORING	COMMENTS
Quality Improvement Project/Health Care Study Evaluation			
III.	**Review the Selected Study Indicator(s): A study indicator is a quantitative or qualitative characteristic or variable that reflects a discrete event (e.g., an older adult has not received an influenza vaccination in the last 12 months) or a status (e.g., a member's blood pressure is or is not below a specified level) that is to be measured. The selected indicators should track performance or improvement over time. The indicators should be objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research. The study indicators:**		
C	1. Are well-defined, objective, and measurable. ***NA*** is not applicable to this element for scoring.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
—	2. Are based on current, evidence-based practice guidelines, pertinent peer-reviewed literature, or consensus expert panels.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
C	3. Allow for the study question to be answered. ***NA*** is not applicable to this element for scoring.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
—	4. Measure changes (outcomes) in health or functional status, member satisfaction, or valid process alternatives. ***NA*** is not applicable to this element for scoring.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
C	5. Have available data that can be collected on each indicator. ***NA*** is not applicable to this element for scoring.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
—	6. Are nationally recognized measures, such as HEDIS technical specifications, when appropriate. The scoring for this element will be ***Met* or *NA*.**	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	

EVALUATION ELEMENTS		SCORING	COMMENTS
Quality Improvement Project/Health Care Study Evaluation			
III.	**Review the Selected Study Indicator(s): A study indicator is a quantitative or qualitative characteristic or variable that reflects a discrete event (e.g., an older adult has not received an influenza vaccination in the last 12 months) or a status (e.g., a member's blood pressure is or is not below a specified level) that is to be measured. The selected indicators should track performance or improvement over time. The indicators should be objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research. The study indicators:**		
—	7. Includes the basis on which indicator(s) was adopted, if internally developed.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	

Results for Activity III

Total Evaluation Elements					Critical Elements				
Total Evaluation Elements	*Met*	*Partially Met*	*Not Met*	*NA*	Critical Elements	*Met*	*Partially Met*	*Not Met*	*NA*
7	0	0	0	0	3	0	0	0	0

EVALUATION ELEMENTS		SCORING	COMMENTS
Quality Improvement Project/Health Care Study Evaluation			
IV.	**Review the Identified Study Population: The selected topic should represent the entire eligible Medicaid-enrolled population, with systemwide measurement and improvement efforts to which the study indicators apply. The study population:**		
C	1. Is accurately and completely defined. ***NA*** is not applicable to this element for scoring.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
—	2. Includes requirements for the length of a member's enrollment in the MCP.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
C	3. Captures all members to whom the study question applies. ***NA*** is not applicable to this element for scoring.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	

Results for Activity IV

Total Evaluation Elements				
Total Evaluation Elements	*Met*	*Partially Met*	*Not Met*	*NA*
3	0	0	0	0

Critical Elements				
Critical Elements	*Met*	*Partially Met*	*Not Met*	*NA*
2	0	0	0	0

EVALUATION ELEMENTS		SCORING	COMMENTS
Quality Improvement Project/Health Care Study Evaluation			
V.	**Review Sampling Methods: (This activity is scored only if sampling is used.) If sampling is used to select members of the study, proper sampling techniques are necessary to provide valid and reliable information on the quality of care provided. The true prevalence or incidence rate for the event in the population may not be known the first time a topic is studied. Sampling methods:**		
—	1. Consider and specify the true or estimated frequency of occurrence.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
—	2. Identify the sample size.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
—	3. Specify the confidence level.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
—	4. Specify the acceptable margin of error.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
C	5. Ensure a representative sample of the eligible population.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
—	6. Are in accordance with generally accepted principles of research design and statistical analysis.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	

Results for Activity V

Total Evaluation Elements

Total Evaluation Elements	*Met*	*Partially Met*	*Not Met*	*NA*
6	0	0	0	0

Critical Elements

Critical Elements	*Met*	*Partially Met*	*Not Met*	*NA*
1	0	0	0	0

EVALUATION ELEMENTS		SCORING	COMMENTS
Quality Improvement Project/Health Care Study Evaluation			
VI.	**Review Data Collection Procedures: Data collection must ensure that the data collected on the study indicators are valid and reliable. Validity is an indication of the accuracy of the information obtained. Reliability is an indication of the repeatability or reproducibility of a measurement. Data collection procedures include:**		
—	1. The identification of data elements to be collected. ***NA*** is not applicable to this element for scoring.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
—	2. The identification of specified sources of data. **NA** is not applicable to this element for scoring.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
—	3. A defined and systematic process for collecting baseline and remeasurement data. ***NA*** is not applicable to this element for scoring.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
—	4. A timeline for the collection of baseline and remeasurement data. ***NA*** is not applicable to this element for scoring.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
—	5. Qualified staff and personnel to abstract manual data.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
C	6. A manual data collection tool that ensures consistent and accurate collection of data according to indicator specifications.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
—	7. A manual data collection tool that supports interrater reliability.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
—	8. Clear and concise written instructions for completing the manual data collection tool.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
—	9. An overview of the study in written instructions.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
—	10. Administrative data collection algorithms/ flow charts that show activities in the production of indicators.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	

EVALUATION ELEMENTS		SCORING	COMMENTS
Quality Improvement Project/Health Care Study Evaluation			
VI.	**Review Data Collection Procedures: Data collection must ensure that the data collected on the study indicators are valid and reliable. Validity is an indication of the accuracy of the information obtained. Reliability is an indication of the repeatability or reproducibility of a measurement. Data collection procedures include:**		
—	11. An estimated degree of administrative data completeness. *Met* =80–100 percent *Partially Met* =50–79 percent *Not Met* =<50 percent or not provided	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	

Results for Activity VI

Total Evaluation Elements				
Total Evaluation Elements	*Met*	*Partially Met*	*Not Met*	*NA*
11	0	0	0	0

Critical Elements				
Critical Elements	*Met*	*Partially Met*	*Not Met*	*NA*
1	0	0	0	0

EVALUATION ELEMENTS		SCORING	COMMENTS
Quality Improvement Project/Health Care Study Evaluation			
VII.	**Assess Intervention and Improvement Strategies: Real, sustained improvements in care result from a continuous cycle of measuring and analyzing performance, as well as, developing and implementing systemwide improvements in care. Interventions are designed to change behavior at an institutional, practitioner, or member level. The improvement strategies are:**		
C	1. Related to causes/barriers identified through data analysis and quality improvement processes. ***NA*** is not applicable to this element for scoring.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
__	2. System changes that are likely to induce permanent change.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
__	3. Revised if the original interventions are not successful.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
__	4. Standardized and monitored if interventions are successful.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	

Results for Activity VII

Total Evaluation Elements				
Total Evaluation Elements	*Met*	*Partially Met*	*Not Met*	*NA*
4	0	0	0	0

Critical Elements				
Critical Elements	*Met*	*Partially Met*	*Not Met*	*NA*
1	0	0	0	0

EVALUATION ELEMENTS		SCORING	COMMENTS
Quality Improvement Project/Health Care Study Evaluation			
VIII.	**Review Data Analysis and the Interpretation of Study Results: Review the data analysis process for the selected clinical or nonclinical study indicators. Review appropriateness of, and adherence to, the statistical analysis techniques used. The data analysis and interpretation of the study results:**		
—	1. Are conducted according to the data analysis plan in the study design. ***NA*** is not applicable to this element for scoring.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
C	2. Allow for the generalization of results to the study population if a sample was selected. If sampling was not used this score will be ***NA*.**	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
—	3. Identify factors that threaten the internal or external validity of findings. ***NA*** is not applicable to this element for scoring.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
—	4. Include an interpretation of findings. ***NA*** is not applicable to this element for scoring.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
C	5. Are presented in a way that provides accurate, clear, and easily understood information. ***NA*** is not applicable to this element for scoring.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
—	6. Identify the initial measurement and the remeasurement of the study indicators.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
—	7. Identify statistical differences between the initial measurement and the remeasurement.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
—	8. Identify factors that affect the ability to compare the initial measurement with the remeasurement.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	

EVALUATION ELEMENTS		SCORING	COMMENTS
Quality Improvement Project/Health Care Study Evaluation			
VIII.	**Review Data Analysis and the Interpretation of Study Results: Review the data analysis process for the selected clinical or nonclinical study indicators. Review appropriateness of, and adherence to, the statistical analysis techniques used. The data analysis and interpretation of the study results:**		
—	9. Include an interpretation of the extent to which the study was successful.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	

Results for Activity VIII

Total Evaluation Elements				
Total Evaluation Elements	*Met*	*Partially Met*	*Not Met*	*NA*
9	0	0	0	0

Critical Elements				
Critical Elements	*Met*	*Partially Met*	*Not Met*	*NA*
2	0	0	0	0

EVALUATION ELEMENTS		SCORING	COMMENTS
Quality Improvement Project/Health Care Study Evaluation			
IX.	**Assess for Real Improvement: Through repeated measurement of the quality indicators selected for the project, meaningful change in performance relative to the performance observed during baseline measurement must be demonstrated. Assess for any random, year-to-year variations, population changes, or sampling errors that may have occurred during the measurement process.**		
—	1. The remeasurement methodology is the same as the baseline methodology.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
—	2. There is documented improvement in processes or outcomes of care.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
—	3. The improvement appears to be the result of planned intervention(s).	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	
—	4. There is statistical evidence that observed improvement is true improvement.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	

Results for Activity IX

Total Evaluation Elements				
Total Evaluation Elements	*Met*	*Partially Met*	*Not Met*	*NA*
4	0	0	0	0

Critical Elements				
Critical Elements	*Met*	*Partially Met*	*Not Met*	*NA*
0	0	0	0	0

EVALUATION ELEMENTS		SCORING	COMMENTS
Quality Improvement Project/Health Care Study Evaluation			
X.	**Assess for Sustained Improvement: Assess for any demonstrated improvement through repeated measurements over comparable time periods. Assess for any random, year-to-year variations, population changes, or sampling errors that may have occurred during the remeasurement process.**		
—	1. Repeated measurements over comparable time periods demonstrate sustained improvement or that a decline in improvement is not statistically significant.	☐ *Met* ☐ *Partially Met* ☐ *Not Met* ☐ *NA*	

Results for Activity X

Total Evaluation Elements				
Total Evaluation Elements	*Met*	*Partially Met*	*Not Met*	*NA*
1	0	0	0	0

Critical Elements				
Critical Elements	*Met*	*Partially Met*	*Not Met*	*NA*
0	0	0	0	0

Appendix C. California Medi-Cal Managed Care Program
QIP Validation Tool:
<QIP Topic>
for <Full Name>

Table C-1—QIP Validation Summary Scores *for* <QIP Topic> *for* <Full Name>										
Review Steps	**Total Possible Evaluation Elements** (Including Critical Elements)	**Total *Met***	**Total *Partially Met***	**Total *Not Met***	**Total *NA***	**Total Possible Critical Elements**	**Total Critical Elements *Met***	**Total Critical Elements *Partially Met***	**Total Critical Elements *Not Met***	**Total Critical Elements *NA***
I. Review the Selected Study Topic	6					1				
II. Review the Study Question(s)	2					2				
III. Review the Selected Study Indicators	7					3				
IV. Review the Identified Study Population	3					2				
V. Review Sampling Methods	6					1				
VI. Review Data Collection Procedures	11					1				
VII. Assess Improvement Strategies	4					1				
VIII. Review Data Analysis and the Interpretation of Study Results	9					2				
IX. Assess for Real Improvement	4					No Critical Elements				
X. Assess for Sustained Improvement	1					No Critical Elements				
Totals for All Activities	**53**					**13**				

Table C-2—QIP Validation Summary Overall Score *for* <QIP Topic> *for* <Full Name>	
Percentage Score of Evaluation Elements *Met**	%
Percentage Score of Critical Elements *Met***	%
Validation Status***	***<Met, Partially Met, or Not Met>***

* The percentage score for all evaluation elements *Met* is calculated by dividing the total *Met* by the sum of all evaluation elements *Met, Partially Met*, and *Not Met*.
** The percentage score for critical elements *Met* is calculated by dividing the total critical elements *Met* by the sum of the critical elements *Met*, *Partially Met*, and *Not Met*.
*** *Met* equals confidence/high confidence that the QIP was valid.
Partially Met equals low confidence that the QIP was valid.
Not Met equals reported QIP results that were not credible.

EVALUATION OF THE OVERALL VALIDITY AND RELIABILITY OF QIP RESULTS
HSAG assessed the implications of the study's findings on the likely validity and reliability of the results based on the CMS protocol for validating QIPs. HSAG also assessed whether the State should have confidence in the reported QIP findings.
***Met* = Confidence/high confidence in the reported QIP results** ***Partially Met* = Low confidence in the reported QIP results** ***Not Met* = Reported QIP results that were not credible**
Summary of Aggregate Validation Findings ☐ ***Met*** ☐ ***Partially Met*** ☐ ***Not Met***

Summary statement on the validation findings:
Activities xx through xx were assessed for this QIP validation summary. Based on the validation of this QIP, HSAG's assessment determined xx confidence in the results.

☐ For this QIP proposal, the results of the QIP appear to be valid and reliable. The plan should proceed with the study and submit baseline results no later than _____.

☐ For this validation cycle, the results of the QIP appear to be valid and reliable. The plan will continue with the QIP and submit the annual submission no later than _____. The plan should address all *Points of Clarification*, *Partially Met*, or *Not Met* evaluation elements.

☐ For this validation cycle, the results of the QIP do not appear valid and reliable. The plan is directed to resubmit the revised QIP documentation to address all *Points of Clarification, Partially Met*, and *Not Met* evaluation elements no later than _____.

☐ For this validation cycle, the results of the QIP appear to be valid and reliable. This is the final submission of the QIP. The plan should now submit a new proposal to DHCS for approval by _____.